Exhibit 204

Expert Report of Steven W. Baertschi, Ph.D.
***In re: Valsartan Products Liability Litigation*, MDL No. 2875 (D.N.J.)**

I. Introduction

1. This report is offered pursuant to Rule 26 of the Federal Rules of Civil Procedure. Each of the opinions I have offered in this report is given to a reasonable degree of scientific certainty and is based on scientific methods and procedures, the materials I have reviewed in connection with this litigation, as well as my education, training, knowledge, and experience. I reserve the right to supplement the list of materials reviewed, as well as to amend and supplement the opinions expressed in this report. I also reserve the right to respond to and rebut all information provided in discovery, which I understand is ongoing, and any opinions offered by Plaintiffs' experts at their depositions or at trial.

2. Citations to specific reference material are offered in this report where I believe it necessary to cite a specific source. Otherwise, my opinions are derived from a combination of reference sources and my own scientific knowledge. This report is not meant to be an exhaustive recitation of all of my opinions as I understand my opinions will be more fully explored at my deposition. My curriculum vitae is attached to this report as Exhibit A.

3. A list of materials that I considered in rendering the opinions offered in this report is attached as Exhibit B. Because I have reviewed ample scientific literature over my continued education in my field of expertise, it is not possible to list all of the material informing my opinions. I am, however, attaching a list of references that I have reviewed in Exhibit B. By including literature on this list, it does not imply that I place any particular emphasis on the reference or that I agree with all of the content in any particular publication.

4. At the time of trial, I may use other records or graphics to assist with the illustration of my opinions. I reserve the right to amend and further supplement my opinions based on additional material provided to me after the date of this report.

5. I may use at trial any exhibits as a summary or in support of all of my opinions including: (1) any of the materials, or excerpts identified in this report and attachments, including materials considered list; (2) excerpts from scientific articles or learned treatises; (3) demonstrative models; (4) exhibits used by the plaintiff's experts, or other witnesses; (5) the individual plaintiff's records; and (6) any exhibit used in or identified at any deposition take in this Litigation. If further data becomes available, I will be happy to review it and consider whether to modify any portion of these opinions.

6. I have been compensated at the rate of $400.00 per hour for my work on this matter. My fee for deposition / testimony work is $550.00 per hour. I have no conflicts of interest to disclose.

7. I have testified as an expert witness at deposition in the past four years in the following: *Exela Pharma Sciences, LLC v. Eton Pharmaceuticals, Inc.*, District of Delaware, Civil Action No. 1:20-cv-0365-MN, deposed on June 11, 2021, and on December 10, 2021.

II. Qualifications

8. My qualifications and credentials are fully set forth in my curriculum vitae, attached as Exhibit A to this report. I hold a Bachelor of Science degree in Chemistry with a minor in Mathematics from Lipscomb University. I have a Master of Science and a Ph.D. in Organic Chemistry (minor in Biochemistry) from Vanderbilt University. While a graduate student, I received an NIH National Research Service Award for my predoctoral research. A significant portion of my research involved fundamental research of the mutagenicity / carcinogenicity of Aflatoxins. After completing my studies, I began working at Eli Lilly and Company as a Senior Chemist where I was involved in analytical and pharmaceutical product development. I remained at Eli Lilly where I was continually

promoted until I reach the title of Senior Research Fellow, Small Molecule Design and Development. Through these promotions I was involved and became familiar with all aspects of pharmaceutical development. I retired from Eli Lilly in February 2015. Upon my retirement from Eli Lilly, I founded Baertschi Pharmaceutical Consulting, LLC ("BPC") and retain the title of President. Our offices are located at 3967 Chadwick Drive, Carmel, Indiana 46033. At BPC, I have consulted and worked for pharmaceutical, biotech, animal health, and agrochemical organizations working on a wide range of topics including pre-formulation, stability, photostability, and degradation chemistry, analytical and impurity method development and control strategies (including genotoxic / mutagenic impurities), and formulation development. In addition to my academic and work experience, I have authored 59 peer-reviewed articles, nine non-peer reviewed articles, 29 book chapters, and have been an editor of two books and one journal issue. All of my publications are set forth in my curriculum vitae. I have also presented over 140 scientific oral presentations and have chaired or organized over 38 different conferences and symposia, many of these dealing with impurities (including mutagenic / genotoxic) and analytical methodologies. These presentations and conferences are discussed in more detail in my curriculum vitae.

9. A list of my peer-reviewed publications and invited presentations related to topics including, but not limited to, impurities, mutagenic / genotoxic impurities, and analytical methodologies are listed in my curriculum vitae.

10. I was named a Fellow of the AAPS in 2007 for my career contributions to the advancement of Pharmaceutical Sciences. I have taught workshops at the U.S. Pharmacopeial convention, the US-FDA, and at ANVISA (the Brazilian equivalent of FDA). I have served on three different review panels for NASA (for proposals related to the stability of drugs in space). I am on the Editorial Advisory Board for three journals (J. Pharm. Sci., J. Pharm. Biomed. Analysis, and Eur. Pharm. Review). I have served on a grant review panel for NIH for renewal of the National Toxicology Program contract. I was a member of two PhRMA Limited Duration Key Initiative Teams for the development of the ICH M7 mutagenic impurities regulatory guidance. I served on the USP Expert Panel on Impurities (2011-2018) and co-authored the USP chapters <476> and <1086>, "Organic impurities in drug substances and drug products" and "Impurities in drug substances and drug products", respectively.

III. Assignment

11. I have been retained by the Teva Defendants to provide an expert opinion in the litigation styled *In re: Valsartan Products Liability Litigation*, MDL No. 2875 (D.N.J.). Specifically, I was asked by counsel for Teva to assess testing conducted by and testing capabilities available to Teva during the relevant time period and to review and respond to the opinions presented by Plaintiffs' class certification experts.

IV. Executive summary

12. Analyzing low level impurities such as the NDMA and NDEA found in the valsartan medication is extremely difficult and requires specialized analytical testing methods.

13. Drug manufacturers do not and cannot test for every conceivable impurity, and it is particularly difficult to test for impurities at the low levels seen in valsartan.

14. The specification testing for valsartan medication in place prior to July 2018 did not include testing capable of detecting NDMA and NDEA at the levels at issue. Moreover, Teva appropriately and reasonably analyzed its finished dose drug product in connection with the process change implemented for the ZHP API in 2014.

V. Analysis

A. Analyzing low level impurities such as the NDMA and NDEA found in the valsartan medication is extremely difficult and requires specialized equipment, analytical testing methods, and expertise.

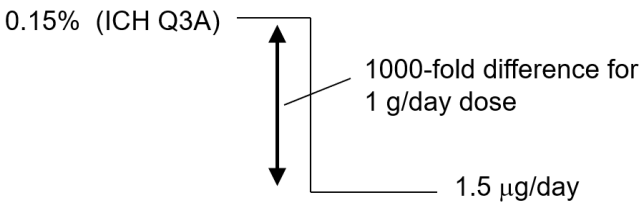
15. The safety and purity of drug substances and their corresponding formulated products is a major concern in the pharmaceutical industry. Acceptable reporting, identification, and qualification levels for impurities in these products is detailed by regulatory guidances first implemented in 1995 (i.e., ICH Q3A and ICH Q3B[1,2]). For synthetic small molecule drug substances such as valsartan (VAL), the threshold for conducting safety / toxicological studies (i.e., the qualification threshold) for an impurity is 0.15% (or 1.0 mg/day intake of the impurity, whichever is lower, see Q3A - Table 1). For the corresponding formulated product, the qualification threshold for 10 mg – 100 mg per day daily dose is 0.5% (or 20 ug/day, whichever is lower) and for 100 mg – 2 g per day daily dose is 0.2% (or 3 mg TDI, whichever is lower). These guidances also state that "lower thresholds can be appropriate if the impurity is unusually toxic", but no further guidance or discussion is provided. While the reference to unusual toxicity could be interpreted as relating to genotoxic impurities, absence of any additional explanation left the industry with an obvious lack of practical guidance in relation to this topic.

16. In 2006, in order to address this gap, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMEA, now known as EMA) issued a "Guideline on the Limits of Genotoxic Impurities".[3] Subsequently, in May of 2015, ICH issued a guidance (ICH M7) that focuses on a subset of genotoxic impurities, namely mutagenic impurities, providing the industry with a more comprehensive guidance for assessing and controlling mutagenic impurities in pharmaceuticals.[4] ICH M7 established thresholds for maximum levels for impurities that are known or suspected to be mutagenic, referred to as the "Threshold of Toxicological Concern (TTC)". The TTC is dependent on the duration of use of the drug; for lifetime use (i.e., >10 yrs), 1.5 ug/day is defined as the limit (the TTC).

17. As described by Delaney,[5] for a pharmaceutical that is dosed at 1 g/day, this 1.5 ug/day threshold represents a 1000-fold difference in the levels for which safety-based control strategies would be needed when compared to ordinary (i.e., non-mutagenic) impurities described by ICH Q3A. This enormous disparity has been termed "the cliff of regulatory concern" because of the potentially dramatic impact on the development of pharmaceutical products as a result of the difficulties associated with developing control strategies (e.g., analytical methods, synthetic routes, formulations, and specifications) for such trace level impurities. As Delaney

points out "[g]iven that side reactions and degradation processes that might be measurable within this range have not been well studied or documented in the scientific literature, it is difficult for process designers to predict with confidence all relevant substances that may exist within the gap between standards."

Figure 1. Illustration of the so-called "regulatory cliff of concern", a 1000-fold difference in qualification thresholds for ordinary impurities (described by ICH Q3A) when compared to the TTC for mutagenic impurities (described by ICH M7).



18. These implications are even more obvious when considering the three classes of potential high potency mutagens referred to as the "Cohort of Concern" (CoC), which comprises aflatoxin-like-, N-nitroso-, and alkyl-azoxy compounds. In the case of the CoC impurities, the thresholds for carcinogenic risk may be adjusted to significantly lower than the 1.5 ug (1,500 ng)/day TTC value, and less than lifetime approaches to N-nitrosamine impurities are not recommended by CHMP.[6] Such is the case for NDMA and NDEA, whereas of December 2018, the threshold limits were established by FDA and EMA as 96.0 ng/day and 26.5 ng/day, respectively (see Table 1 immediately below). As illustrated by the calculations immediately below,

these levels are 15,600 times and 56,600 times lower than ICH Q3A qualification thresholds, respectively.

- For a 1 g/day drug dose, the limits for NDEA and NDMA:
  - 1,500 ng / day divided by 26.5 ng/day (NDEA, which corresponds to 0.082 ppm in a 320 mg VAL dose) = 56.6x less x 1000 = 56,600 x less than Q3A
  - 1,500 ng / day divided by 96.0 ng/day (NDMA, which corresponds to 0.300 ppm in a 320 mg VAL dose) = 15.6 x less x 1000 = 15,600 x less than Q3A

Table 1 from the EMA Lessons Learnt document,[7] showing the limits for NDMA and NDEA set during Article 31 review.

Table 1. Temporary limits for NDMA and NDEA impurities set during Article 31 review.

	NDMA		NDEA	
Active substance (max daily dose)	**Maximum daily intake (ng)**	**Limit (ppm)**	**Maximum daily intake (ng)**	**Limit (ppm)**
Candesartan (32 mg)	96.0	**3.000**	26.5	**0.820**
Irbesartan (300 mg)	96.0	**0.320**	26.5	**0.088**
Losartan (150 mg)	96.0	**0.640**	26.5	**0.177**
Olmesartan (40 mg)	96.0	**2.400**	26.5	**0.663**
Valsartan (320 mg)	96.0	**0.300**	26.5	**0.082**

19. For ordinary,[8] non-mutagenic impurities, ICH Q3A and Q3B define the thresholds for impurity levels (see for example Q3A - Table 1, below), and the impurity control strategies are developed using ICH Q1-Q14 guidelines. Analytical methodologies to ensure purity (impurities) and

potency (assay) are typically developed with sufficient resolution (to resolve impurities from each other and from the parent drug) and sensitivity (detection limit, quantification limit) to cover the Q3A/B thresholds. Typically, for pharmaceutical impurities, HPLC with UV detection is by far the analytical separation / detection technique of choice.[9] Limits of detection (LOD) with this methodology are typically below the reporting thresholds of 0.05% and can often achieve 0.01% (where 0.01% is 100 ppm).

Q3A - Table 1: Impurities in new drug substances thresholds

Table 1
Q3A(R): Impurities in new drug substances

Maximum daily dose[a] (g)	Reporting threshold[b,c] (%)	Identification threshold[c]	Qualification Threshold[c]
< or = 2	0.05	0.10% or 1.0 mg per day intake (whichever is lower)	0.15% or 1.0 mg per day intake (whichever is lower)
>2	0.03	0.05%	0.05%

[a] The amount of drug substance administered per day.
[b] Higher reporting thresholds should be scientifically justified.
[c] Lower thresholds can be appropriate if the impurity is unusually toxic.

20. It is worth comparing the impurity identification thresholds for ICH Q3A / B with the various less than lifetime or staged-TTC (sTTC, where "staged" indicates the TTC levels for various lengths of dosing regimens) values. In Figure 2, below, those numbers highlighted in green correspond to impurity levels that are readily covered by typical HPLC-UV impurities methods; those numbers highlighted in yellow are on the borderline; those numbers highlighted in red would require "out of the ordinary" challenges for

detection and quantification using HPLC-UV. This means that specialized methods would need to be developed in order to detect and quantify such low-level impurities as those highlighted in red on the Figure 2 table. This is especially true for NDEA and NDMA in sartan, where the limits are 0.3 ppm for NDMA and 0.082 ppm for NDEA (see Table 1 from EMA Lessons Learnt document). Compared to an LOD of 0.1% (the practical limit for typical HPLC UV impurities methods), methods to detect NDMA would need to be at least 333 times more sensitive (0.01% = 100 ppm; 100 ppm / 0.3 ppm = 333) and methods to detect NDEA would need to be at least 1220 times more sensitive (0.01% = 100 ppm; 100 ppm / 0.082 ppm = 1220).

Figure 2. Comparison of ICH identification thresholds for impurities in the DS and DP and the concentrations of impurities calculated from the FDA-staged TTC values for various daily doses of drug.[9]

Analytical Complexity as a Function of Dose

Daily Dose (mg)	ICH Identification Thresholds (%)		Maximum Concentration of Genotoxic Degradants Calculated from the Less-than-Lifetime Values (%)			
	DS	DP	≤ 1 month (120 ug)	> 1 – 12 months (20 ug)	> 1 – 10 years (10 ug)	> 10 years to lifetime (1.5 ug)
3000	0.05	0.1	0.004	0.00067	0.00033	0.00005
1000	0.1	0.2	0.012	0.002	0.0001	0.00015
300	0.1	0.2	0.04	0.0067	0.0033	0.0005
100	0.1	0.2	0.12	0.02	0.01	0.0015
30	0.1	0.2	0.4	0.067	0.033	0.005
10	0.1	0.2	1.2	0.2	0.1	0.015
3	0.1	0.5	4	0.67	0.33	0.05
1	0.1	0.5	12	2	1	0.15
0.3	0.1	1	40	6.7	3.3	0.5

Green: Standard HPLC-UV method will likely be suitable for controlling GTI
Yellow: Standard HPLC-UV method may be suitable, but a more sensitive (e.g., LC-MS) method may be required
Red: A more sensitive (e.g., LC-MS) method may be required for controlling GTI

21. The challenges associated with analytical methods for such low-level impurities in pharmaceutical products has been discussed extensively in the literature.[10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26] From these articles, which is by no means an exhaustive review of the literature, it is clear that there is a widespread alignment that specialized, non-routine, highly selective and sensitive analytical methodologies are required for trace level detection and quantification of mutagenic impurities.

22. As stated in Liu et al.: "Rapid development of extremely sensitive and robust analytical methodologies that can adequately monitor GTIs at very low levels is technically challenging."[15] Liu continues: "The biggest challenge lies in the need for high method sensitivity and selectivity, so that matrix interferences from APIs or excipients in the case of formulated drug products can be overcome. Although simplified separation and detection methodologies are desired in the manufacturing quality control laboratories, MS detection coupled with GC or HPLC plays a critical role in trace GTI analysis in various stages of pre-clinical and clinical drug development. This is primarily driven by the non-routine requirement of method sensitivity, specificity, and speed of method development needed for project support." It is thus recognized by Liu that the detection and identification of specific trace impurities cannot be an expected outcome of routine impurities screening and analysis.

23. Al Azzam, et al. explain: "Unlike other, well-established fields, where trace analysis is employed, for example pesticide residue analysis, the matrix properties of genotoxic impurities can often be similar to that of the analyte; this is particularly true for 'API-like' genotoxic compounds, such as late-stage intermediates."[22] The article continues: "Certainly, in terms of pharmaceuticals, the limits associated with genotoxic impurities are often

significantly lower than anything previously measured, by up to three orders of magnitude. . . . Finally, by their very nature, many of the (very diverse range of) genotoxic analytics are highly reactive and thus prone to degradation during the analysis, making analysis and particularly quantification challenging in many instances." It is thus clear that, in the context of pharmaceuticals, identifying a particular trace compound is extremely difficult and unlikely without advanced knowledge of the nature of the compound being investigated.

24. As described by Baker, et al.,[24] and supported by recommendations from Dow, et al.,[26] analytical methods for genotoxic impurities should target a detection limit of 10% of the TTC or threshold established for the particular genotoxic impurity. Further, as explained in Baker, "if 10% of the limit is not analytically achievable with due diligence, a limit of quantitation (LOQ) less than the limit, or as low as reasonably practicable, should be established to support the limit." The target detection levels for mutagenic impurities are significantly higher than the detection limits that would be needed for the NDMA and NDEA impurities at issue in valsartan medications.

25. Teasdale and Elder discuss the significant analytical challenges in terms of the low limits / sensitivity, matrix interference, and the diverse

physicochemical properties of the mutagenic impurities.[12] A method selection process map is suggested in this article, and this map illustrates some of the complexities involved in developing appropriate, sensitive, and selective methods for specific mutagenic impurities. It is noteworthy that the starting point for this process map requires a known structure / compound, with known properties; the map does not deal with the discovery (i.e., the initial analytical detection and structure elucidation) of an unknown or unexpected potentially genotoxic impurity. Rather, it illustrates the complexities and decision-making process that is involved in developing an analytical method sensitive enough to detect and quantify a **known** compound at the very low levels required. Without knowledge of the existence of a particular compound, detection at the low levels seen here would be well outside the scope of industry best practices.

Figure 1. A method selection process chart for developing appropriate analytical methods for mutagenic impurities.

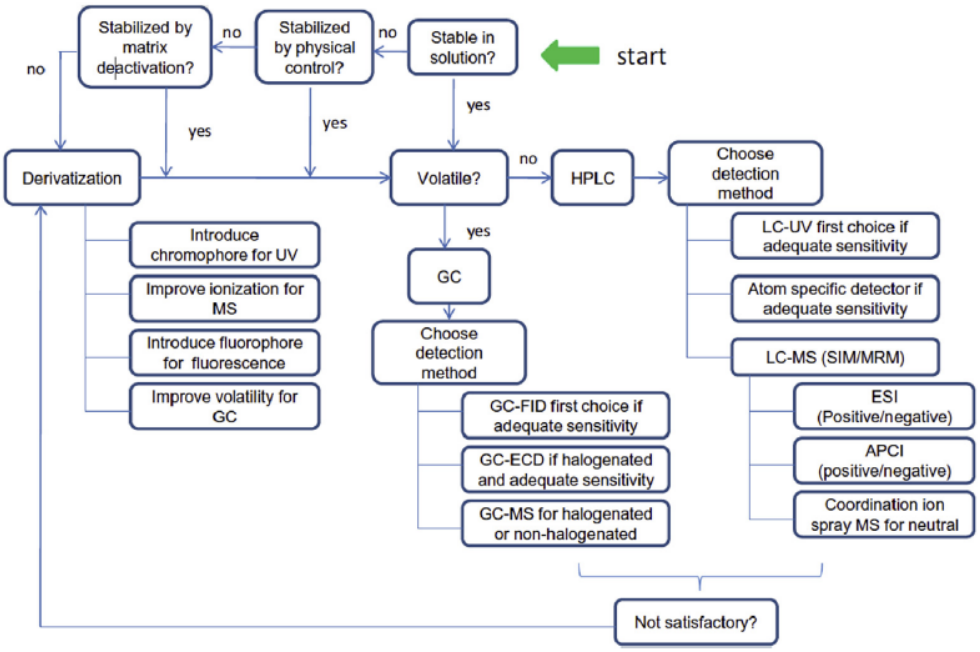


Fig. 3. Method selection process.

26. These difficulties in detecting trace impurities are significantly increased for CoC impurities such as N-nitrosamines, which require even more sensitivity than "typical" mutagenic impurities. This has been addressed by Reddy, et al., with regard to small molecule N-nitroso compounds such as NDMA and NDEA: "[I]t should be stated that in all cases the levels are in the order of ng/day which necessitates the need for highly sensitive and selective detection systems to be employed. This has resulted in the routine use of mass spectrometry in the analysis of this class of mutagenic compounds. Although mass spectrometers are used routinely within the pharmaceutical market, they

are not typically used for routine quantitative analysis within final product testing. This has resulted in a range of challenges that need to be addressed, that are not present with other detectors, such as UV."[25] The authors further examine "[t]he presence of residual DMF, which has been reported to potentially lead to errors in the quantification of NDMA in drug products" and note that "[t]he separation of nitrosamines can be achieved by reversed phase LC (RPLC), although given their hydrophilic, polar nature, retention of some nitrosamines can be challenging." They conclude: "As previously stated, the low detection limits required necessitates the use of highly sensitive and highly specific detectors, such as mass spectrometry, although the low molecular weight of nitrosamines and their relatively low hydrophobicity can make developing a sensitive and robust method somewhat challenging. . . . The low acceptable daily intake limits established for nitrosamines, which must be considered against the maximum API daily dose, requires the application of highly sensitive and selective MS detection, capable of quantification at the low ppb level."

B. Drug manufacturers do not and cannot test for every conceivable impurity, and it is particularly difficult to test for impurities at the low levels seen in valsartan.

27. As I have established above, it is clear that the approved analytical impurity methods for valsartan did not have the sensitivity to detect NDMA or NDEA at the low levels ultimately detected in valsartan products. It is worth further considering the implications of the expectation that the analytical impurity methods associated with valsartan, or any pharmaceutical product, would / should / could detect any or all genotoxic / mutagenic impurities that could conceivably be present in any given product.

28. It should first be acknowledged that the presence of N-nitroso impurities in pharmaceutical products was unexpected. This is confirmed by examination of EMA and FDA documents which repeatedly assert this fact (*see* for example notes 7 and 27).

29. Next, it should be acknowledged that it is not realistic to expect that compendial analytical impurity methods will detect all potentially genotoxic / mutagenic impurities at levels of concern, because of the large numbers and sheer diversity of such potential impurities. Such an expectation would require the analytical methods not only to detect specific mutagenic impurities (such as NDMA and NDEA), but also any impurity in the N-nitroso class of impurities.

30. Further, such an expectation would require analytical methods to detect all other classes of mutagenic / carcinogenic impurities. The enormity of such an expectation is illustrated by Benigni and Bossa, who compiled a list of structure alerts (substructures of carcinogenic concern present in molecular structures of compounds) for carcinogenicity, documenting 31+ diverse classes of such compounds.[28] At a minimum, analytical methods unique to the drug substance under investigation would have to be developed for each class of compound. Even then, either certain compounds within each class would evade detection, or multiple analytical methods would need to be developed within any number of classes. It is therefore unrealistic to expect that analytical impurity methods should be able to detect any or all genotoxic / mutagenic impurities that could conceivably be present in a given product. This reality is reflected in standard industry practice and regulatory oversight, which does not approach or require anything near this breadth of specific impurity analytical impurity testing.

C. The specification testing for valsartan medication in place prior to July 2018 did not include testing capable of detecting NDMA and NDEA at the levels at issue. Moreover, Teva appropriately and reasonably analyzed its finished dose drug product in connection with the process change implemented for the ZHP API in 2014 and 2014.

31. The certificates of analysis for valsartan drug substance on Feb 9, 2015 (the date that Watson Laboratories submitted a CBE-30 supplement

to the FDA for the process changes made by ZHP), as found in TEVA-MDL287500013107, showed results for the analysis of three lots of valsartan made by the "currently approved process" as well as three lots from the "proposed process." The same analysis is shown in the CBE-30 supplement letter dated Sept 9, 2014, as found in TEVA-MDL2875-00001886. The results show that all of the lots, including the lots from the "proposed process" met all specifications, including the specifications for purity (as shown by the related substances results), with no detected impurities either (a) above the limit of quantitation or (b) above the specification for any other individual impurity < or = 0.10% (where 0.10% = 1000 ppm).

32. Similar conclusions about the ability of compendial impurity methods to detect low levels of NDMA or NDEA can be made by looking at the pharmacopeial methods listed in the USP monographs for valsartan tablets, valsartan and amlodipine Tablets, and valsartan and Hydrochlorothiazide tablets. These analytical methods for impurities utilize HPLC with UV detection: for valsartan tablets with a disregard for any peaks < or = 0.05%; for valsartan / amlodipine tablets, with a disregard for any peaks < or = 0.1%; for valsartan / hydrochlorothiazide tablets, UV detection with a disregard for any peaks < or = 0.2%). It is clear that these compendial methods

are not appropriate for detection and reporting of levels of NDMA or NDEA at levels below 1000 ppm (or 0.1%).[29]

33. As was described in a Chemical and Engineering News ("C&EN") article in 2019, the FDA told C&EN that "the impurities were hard to detect using the analytical methods provided by the manufacturers, especially given the compounds' low concentrations".[30] The article further states that "the problem is you're not going to see it if you don't know that it's going to be there", clearly implying that routine impurity methods are not suitable, and, rather, specialized, focused methods would have been needed to discover the presence of these specific N-nitroso impurities. This article further illustrates the wide recognition that the analytical methodologies in place at the time would not be able to detect, let alone quantify, such low levels of NDMA or NDEA as those detected in valsartan products.

34. Further, after reviewing the change control instance report (May 21, 2013, TEVA-MDL2875-00950662), the CBE-30 supplement letter (Sept 9, 2014, TEVA-MDL2875-00001886), the FDA approval letter (notification of completion of the review and "approval" of the sANDA by FDA to Watson Laboratories, Sept 29, 2014, TEVA-MDL2875-00133642), and the CBE-30 supplement letter (Jan 9, 2015, TEVA-MDL2875-00013107), it appears clear to me that Teva (i.e., Watson at the time) appropriately and reasonably

analyzed the finished dose product in connection with the process change implemented by ZHP API in 2014 and approved by the FDA. To the extent Plaintiffs suggest these impurities should have been identified as part of the change control evaluation,[31] the analysis undertaken by Teva / Watson was consistent with the expectations of regulators and standard industry practice.

35. Plaintiffs have asserted that in order for a generic product to be considered the "same" product, the "chemical composition" must be "identical".[32] They seem to imply that any differences in impurity profile and impurity levels, regardless of the levels or differences in levels, render the generic product to not be the "same" as the RLD. If this were true, it would mean that every lot of a product produced, even by the same manufacturer, could qualify as a "different" product, since variations in levels of impurities present are a reality allowed by the specifications that are approved by regulatory authorities; this is especially true if trace levels of impurities are included in the consideration. The levels of impurities found in valsartan medications as a result of NDMA and NDEA were within the limits of the specifications approved by the FDA at all times that Teva's valsartan-containing medications were provided to patients.

VI. Conclusions

36. It is inherently difficult to analyze low level impurities such as the NDMA and NDEA found in valsartan medications. Identification and quantification of these impurities and requires specialized analytical testing methods that are well-outside the scope of standard impurities testing and screening for impurities generally and for mutagenic / carcinogenic impurities specifically. The levels of impurities seen here in valsartan products are thousands of times smaller than those which would be identified by ordinary methods of general impurities detection. Even if more sensitive screening for mutagenic / carcinogenic impurities were employed, the trace levels of NDMA and NDEA impurities, as defined by the limits recommended by FDA, in valsartan would be 333 (NDMA) and 1220 (NDEA) times too low to be detected by these methods.

37. Drug manufacturers do not and cannot test for every conceivable impurity. The wide variety and sheer number of classes of potential mutagenic / carcinogenic impurities makes specialized analytical testing for impurities at the trace levels seen here impossible from a practical point of view. Accordingly, regulators historically do not routinely expect or require such testing.

38. As discussed in detail above, the specification testing for valsartan medications in place prior to July 2018 did not include testing capable of detecting NDMA and NDEA at the levels ultimately detected in valsartan products. Moreover, Teva appropriately and reasonably analyzed its finished dose drug products in connection with the process change implemented for the ZHP API in 2014.

Dated: January 12, 2022

Steven W. Baertschi, Ph.D.

[1] ICH (International Committee for Harmonization), 2002. Guideline Q3A(R2): Impurities in New Drug Substances (Revised Guideline).
[2] ICH (International Committee for Harmonization), 2002. Guideline Q3A(R2): Impurities in New Drug Products (Revised Guideline).
[3] European Medicines Agency (EMEA). 2006. Guideline on the limits of genotoxic impurities. EMEA/CHMP/QWP/251344/ 2006, London, UK. Accessed January 23, 2013, at: http:// www.emea.europa.eu/pdfs/human/swp/519902en.pdf.
[4] ICH (International Committee for Harmonization), M7 Assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk, May 2015 (revised to R1 in Mar of 2018).
[5] Delaney EJ, "An impact analysis of the application of the threshold of toxicological concern concept to pharmaceuticals", Reg. Toxicol. Pharmacol. 49, 107-124 (2007).

[6] European Medicines Agency, 25 June 2020, EMA/369136/2020, Assessment report, Nitrosamine impurities in human medicinal products, procedure number: EMA/H/A-5(3)/1490, Section 4.3.3, p. 76 of 90.

[7] Lessons learnt from presence of N-nitrosamine impurities in sartan medicines, 23 June 2020, EMA/526934/2019.

[8] The United States Pharmacopeia defines ordinary impurities as "those species in drug substances and/or drug products that have no significant, undesirable biological activity in the amounts present. These impurities may arise out of the synthesis, preparation, or degradation of compendial articles."

[9] Baertschi SW, Olsen BA, "Mutagenic Impurities", in Specification of Drug Substances and Drug Products: Development and Validation of Analytical Methods, Second Edition, Riley CM, Rosanske TW, Reid GL, Editors, Elsevier, New York, p. 332 (2019).

[10] Pierson, D. A.; Olsen, B. A.; Robbins, D. K.; DeVries, K. M.; Varie, D. L. Approaches to Assessment, Testing Decisions, and Analytical Determination of Genotoxic Impurities in Drug Substances. Org. Process Res. Dev. 2009, 13 (2), 285-291.

[11] Liu, D. Q.; Korda, A. S. Analytical Challenges in Stability Testing for Genotoxic Impurities. Trends Anal. Chem.2013, 49, 108-117.

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[31] *See* Expert Declaration of Ron Najafi, Ph.D., §§ 22, 24.

[32] *See* Expert Declaration of Ron Najafi, Ph.D., §§ 14, 15, 18, 32, 33.

EXHIBIT A

CURRICULUM VITAE
Steven W. Baertschi, Ph.D., Fellow, AAPS (2007)

Home / Work Address
3967 Chadwick Drive
Carmel, IN 46033
317-616-8779 (personal / business cell)
Email: swbaertschi@gmail.com
Website: baertschiconsulting.com

CURRENT POSITION (since Feb 2015)

President, Baertschi Pharmaceutical Consulting, LLC

Consulting for pharmaceutical, biotech, animal health, agrochemicals, and consumer healthcare industries on a wide range of topics including: pre-formulation, chemical, physical, stability and degradation chemistry, analytical and impurity (including genotoxic / mutagenic impurity) method development and control strategies, formulation development, photostability / photochemistry, and regulatory issues. 32+ years of in-depth scientific / technical experience in pharmaceutical R&D (Chemistry, Manufacturing, and Control). Contracts / Confidentiality Disclosure Agreements have been established and services provided to more than 65 pharma / biotech companies since the company was established.

EDUCATION

Ph.D., **Organic Chemistry**, **Minor: Biochemistry**, July 1989
Vanderbilt University, Nashville, TN
Research Supervisor: Thomas M. Harris, Centennial Professor of Chemistry
Dissertation Title: "Chemical and Biological Studies of Prostanoids and Aflatoxins"
M.S., **Organic Chemistry**, February 1988, Vanderbilt University, Nashville, TN
B.S., **Chemistry**, **Minor: Mathematics**, June 1980
Lipscomb University, Nashville, TN

SUMMARY OF PUBLICATIONS / SCIENTIFIC / INDUSTRY CONTRIBUTIONS

Peer Reviewed Articles: **58** (>3000 citations; h-index 28; i10-index 49)
Non-Peer Reviewed Articles: **9**
Book Chapters: **29**
Editor Roles: **3** (2 Books and 1 Journal issue)
Oral Presentations: **142+**
Conferences, Symposia Chaired / Organized: **38**

EMPLOYMENT HISTORY

Feb 2015 to present	**President**, Baertschi Consulting, LLC
Feb 2015	**Retired** from Eli Lilly and Company

Oct 2012	Promoted to **Senior Research Fellow,** Small Molecule Design and Development.
Oct 2005	Promoted to **Research Fellow**, Analytical Sciences R&D
Oct 2004	Promoted to **Senior Research Advisor**
Jan 2004	Title changed to **Research Advisor**
Jan 2003	Assumed supervision of Thermal Analysis Group
June 2001	Assumed supervision of Microcalorimetry Group
Jan 2001	Promoted to **Senior Research Scientist**
Jan 2000	Assumed role as Confirmation of Structure Team Leader
Jan 1994 to Dec 2000	Promoted to **Research Scientist**
Jan 1991	Assumed leadership for Degradation Chemistry Group
Aug. 1989 to Dec. 1994	Eli Lilly and Company **Senior Chemist**, Analytical Development Pharmaceutical Product Development

Former Positions Descriptions / Responsibilities

Research Fellow (2005) / Senior Research Fellow (2012) – Eli Lilly
Scientific leader in the Small Molecule Design and Development (SMDD) organization (within Product Research and Development). Responsibilities include reviewing, consulting, approving, recommending, and supervising development programs and project team plans. Leadership role on the development and implementation of new and improved technologies, business processes and strategies. Special focus on degradation chemistry and stability-related issues; oversight and consulting for Degradation Chemistry Group including photostability-related investigations and protocols. Responsibility for the analytical technical assessments on LRL Due Diligence assessments of external assets and companies for licensing considerations. Represented SMDD on numerous cross-functional teams and forums. Provided technical oversight for the analytical chemistry and control strategies required to develop products for global markets. Provided scientific mentoring for numerous scientists in SMDD and cross-functionally in Pharmaceutical Product R&D. Responsible for influencing and defining the current and future scientific and technical strategy for the pharmaceutical R&D organization.

<u>Previous Roles at Lilly</u>
Supervision of the Degradation Chemistry Group (1991-2007, 5 scientists). Responsible for directing comprehensive stress testing studies of non-protein pharmaceuticals to predict stability issues and to define chemical and photochemical degradation pathways. Responsibilities include structure elucidation of unknown degradation products and low-level impurities, response factor determination, and investigation of difficult or unusual impurity or [photo]degradation-related problems. Work includes extensive use of purification techniques such as preparative HPLC, as well as coordinating spectroscopic characterization using

techniques such as NMR, MS, LC/MS, IR, and UV. Responsibilities include significant interaction with analytical development scientists, formulation scientists, spectroscopists, synthetic organic process scientists, Toxicology, Regulatory, as well as general analytical aspects of the drug development process. Responsible for stress testing / degradation information for all regulatory documents / NDA submissions. Served as Lilly point person for regulatory issues related to impurities and to photostability issues, especially regarding the International Conference on Harmonization (ICH) efforts on this topic.

Supervision of the Thermal Analysis and Microcalorimetry Group (2001-2006, 3 scientists). Responsible for the solid-state characterization of compounds in ASRD. Techniques included DTA/TGA, DSC, DMA, DEA, and full microcalorimetry capabilities (high sensitivity DSC, isothermal and isoperibol microcalorimetry, etc.).

Confirmation of Structure Team Leader (2000-2006, approx. 10 scientists). Responsibilities included overseeing the formal structure proof of all small molecule candidates, and the authoring of internal technical reports and regulatory documents / NDA submissions.

Photostability testing (1993-2007). Responsible for photostability testing of all small molecule candidates, including testing design and protocol. Design and oversight of all Lilly photostability investigations.

Prior to Lilly:

Graduate School:

Sept. 1985-July 1989	Graduate Student in Organic Chemistry Vanderbilt University, Nashville, TN

•1985-1989: NIH National Research Service Award grantee in a predoctoral training program in environmental toxicology. Research involved extensive hands-on use of various separation techniques, 1- and 2-D NMR, GC/MS, UV, synthetic and derivatization techniques to elucidate structures. Research focused on studying the molecular basis for aflatoxin carcinogenicity, and the biosynthesis and metabolism of certain prostaglandins and fatty acids.

Positions before Graduate School:

Nov. 1981-Aug. 1985	Daily Analytical Laboratories Environmental Analysis / Residue Chemist 6321 W. Candletree Dr Peoria, IL 61615

Supervised organic section of environmental laboratory (four chemists) and developed methods for analysis of organic priority pollutants in a wide variety of sample matrices utilizing GC and GC/MS. Successfully obtained certification by the Illinois EPA for the Superfund Contract Laboratory Program performing as the top organic laboratory in Illinois in competitive evaluation less than six months after installation of first GC/MS.

Jul. 1980-Oct. 1981 Resource Recycling Technologies
Analytical Chemist
Madison, TN

Developed methods for and performed a wide variety of chemical analyses related to both environmental and oil/solvent samples. Experience with AA, GC, GC/MS, and numerous basic wet chemical methods.

PROFESSIONAL MEMBERSHIPS

- Member of the American Chemical Society since 1980.
- Member of the American Association of Pharmaceutical Scientists since 1991; Steering Committee Member for APQ Stability and APQ Impurities Focus Groups, 2007-present.
- Member, International Forced Degradation Community (2020-present).
- Member of the American Pharmacists Association (APhA), 2011-2016.
- Commission Internationale de l'Eclairage (CIE), Topic Chair for Pharmaceutical Photostability, 2003-2009; Committee Member, Expert Working Group for "In-Use Photostability", 2009-2017.
- Pharmaceutical Photostability of Drugs Interest Group, Steering Committee Member since 1999.
- Member of the American Society for Photobiology (ASP), 2003-2015
- Member of the Customer Advisory Council (Weathering / Photostability) for Atlas Materials and Testing (Mount Prospect, IL), 2014.

HONORS/AWARDS

- Designated as a Fellow of the AAPS (2007)
- Expert Reviewer for NASA's Human Exploration and Operations Mission Directorate, "A Terrestrial Model for Deterioration of Pharmaceuticals Stored on the International Space Station" (2021)
- Panel of Experts for NASA Technical Interchange Meeting to evaluate pharmaceutical stability research strategies for long-duration exploration spaceflight (2019)
- Recipient of the Albert Nelson Marquis Lifetime Achievement Award, Marquis Who's Who Publications Board (2018)

- Grant Review Panel Chair for Stability of Drugs in Space (NASA), BRASH 1801, "Test your expired medications" (Sept 2018)
- NIH Grant Review Panel, Committee Member, for NIH / National Tox Program Contract ZES1-RAM-K(C)-2, (2014)
- Member of the Editorial Advisory Board, J. Pharm. Biomed. Analysis, (January 2010 to present
- Member of the Editorial Advisory Board, J. Pharm. Sci. (Nov 2015-present)
- Member of the Editorial Advisory Board, Cogent Medicine (Sept 2016-May 2018)
- Member of the Editorial Advisory Board, European Pharmaceutical Review (July 2019-present).
- Top Referee Award, 2006, J. Pharm. Biomed. Analysis
- Top Referee Award, 2007, J. Pharm. Sci.
- Top Referee Award, 2008, J. Pharm. Biomed. Analysis
- Top Referee Award, 2015, J. Pharm. Sci.
- Top Referee Award, 2019, J. Pharm. Sci.
- Named as a Scientific Advisor to the Editors of J. Pharm. Sci., 2013.
- Chair, AAPS APQ Fellows Selection Committee, 2010-2012.
- Member, AAPS Executive Fellows Selection Committee, 2010-2012.
- Member, PhRMA Limited Duration Key Initiative Team (LDKIT) for Genotoxic / Mutagenic Impurities, ICH M7 Guidance (2010-2016)
- Co-Chair, ICH M7 Degradants Subtopic Group LDKIT (2011-2015)
- Member, ICH M7 Quality Subgroup LDKIT (2011-2015)
- Member, USP Expert Panel on Impurities (2011-2018)
- Co-founder (Alsante KA) and Editor of the Pharmaceutical Drug Degradation Database, http://d3.cambridgesoft.com/, changed to http://d3.arxspan.com (no longer publicly available, as of Oct 2016)
- Lilly Research Laboratories, President's Recognition Award, 1999
- Lilly Research Laboratories, President's Recognition Award, 2001
- Lilly Research Laboratories, Change the World Award, 2001/Q1
- Lilly Research Laboratories, Change the World Award, 2001/Q4
- Lilly Research Laboratories, Change the World Award, 2002/Q4
- Lilly Research Laboratories, Quality Advocate Award, 2003
- NIH National Research Service Award Grantee, Vanderbilt University, 1986-1989

SCIENTIFIC REVIEWER / REFEREE

Regularly serve as a scientific reviewer / referee for the following journals (~20 articles per year), in approximate order of frequency:

- Journal of Pharmaceutical Sciences
- Journal of Pharmaceutical and Biomedical Analysis
- Trends in Analytical Chemistry
- AAPS PharmSciTech
- Pharmaceutical Research

- Molecular Pharmaceutics
- Pharmaceutical Development and Technology
- Photochemistry and Photobiology
- International Journal of Pharmaceutics
- Drug Development Industrial Pharmacy
- Journal of Pharmaceutical Analysis
- Journal of Chromatography A / B
- The PDA Journal of Pharmaceutical Science and Technology
- Chemical Research in Toxicology
- Biomedical Research International
- Medical and Engineering Physics
- Rapid Communications in Mass Spectrometry

SERVICE AS SCIENTIFIC REVIEWER ON Ph.D. COMMITTEES

- Shah Ravi Piyushkumar, National Institute of Pharmaceutical Education and Research, Served as External Reviewer of Dissertation for Ph.D. Committee; Prof. Saranjit Singh, Research Advisor (Ph.D. Pharmaceutical Sciences, 2011).
- Joergen Brustugun, University of. Oslo, Served as First Opponent for Ph.D. Defense (Ph.D. Pharmaceutical Sciences, 2006), Prof. Hanne H. Tonnesen, Research Advisor.

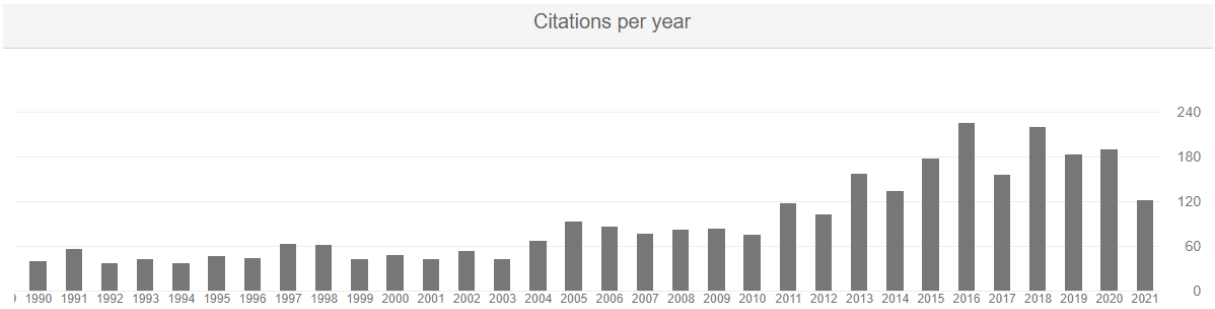
REFERENCES

- Available upon request

PUBLICATIONS

As of Nov 1, 2021; citations 3062; h-index 28; i10-index 49; from My Citations- Google Scholar:

	All	Since 2016
Citations	3062	1102
h-index	28	18
i10-index	49	33



Refereed / Peer Reviewed Publications

60. Hemingway R, Baertschi SW, Benstead DJ, Campbell JM, Coombs MK, Huang Z, Khalaf R, Ott MA, Reid DL, Stevenson NG, Webb SJ, White AT, Zelesky TC, "In silico prediction of pharmaceutical degradation pathways: a benchmarking study using the software program Zeneth, Mol. Pharm., in preparation.

59. Jansen PJ,* Angod M, Clemens M, Kaerner A., and **Baertschi SW**,* "The degradation chemistry of prasugrel hydrochloride. Part 2. Drug product", *J. Pharm. Sci.*, in preparation (2018).

58. Campbell JM,* Foti C,* Wang C, Adams N, Allain LR, Araujo G, Azevedo R, Ribeiro-Franca J, Hicks SR, Hostyn S, Jansen PJ, Kotoni D, Kuemmell A, Marden S, Rullo G, Ana Cláudia O Santos, Sluggett GW, Zelesky T, **Baertschi SW**, "Assessing the relevance of solution phase stress testing of solid dosage form products: a cross-industry benchmarking study", *J. Pharm. Sci.*, accepted, in press, https://www.sciencedirect.com/science/article/abs/pii/S0022354921003026.

57. **Baertschi SW**,* Maxwell-Backer L, Clemens M, Smitka TA, Draper JR, Taylor KW, Kaerner A, and Jansen PJ,* "The degradation chemistry of prasugrel hydrochloride. Part 1. Drug substance, *J. Pharm. Sci*., 108:9, 2842-2857 (2019). https://doi.org/10.1016/j.xphs.2019.04.008

56. **Baertschi SW**, Dill AL, Kramer TT,* Scrivens G,* and Suruzhon M, "Degradation rate observations as a function of drug load in solid state products", *J. Pharm. Sci.*,108, 1746-1755 (2019). https://doi.org/10.1016/j.xphs.2018.12.003.

55. Olsen BA,* Sreedhara A, and **Baertschi SW**, "Impurity investigations by phases of drug and product development", *Trends in Analytical Chemistry*, 101, 17-23 (2018). https://doi.org/10.1016/j.trac.2017.10.025

54. Sluggett G,* Zelesky T, Hetrick E, Babayan Y, and **Baertschi SW**, "Artifactual degradation of secondary amine containing drugs during accelerated stability testing when saturated sodium nitrite solutions are used for humidity control", *J. Pharm. Biomed. Anal.*, 149, 206-213 (2018). https://doi.org/10.1016/j.jpba.2017.10.035

53. Hoaglund Hyzer C,* Williamson ML, Jansen PJ, Montgomery RM, Kopach ME, Scherer RB, and **Baertschi SW**, "Mechanistic Studies of the N-Formylation of Edivoxetine, a Secondary Amine-Containing Drug, in a Solid Oral Dosage Form", *J. Pharm. Sci.*, 106 1218-1238 (2017). http://dx.doi.org/10.1016/j.xphs.2017.01.026

52. Jansen PJ,* Smith WK, Dorman DE, Kemp CAJ, McCune KA, **Baertschi SW**,* "Determination of the Degradation Chemistry of the Anti-Tumor Agent Pemetrexed Disodium", *J. Pharm. Sci.*, 105:11, 3256-3268 (2016). http://dx.doi.org/10.1016/j.xphs.2016.06.029

51. **Baertschi SW**,* Olsen BA, Wozniak TJ, Toltl N, O'Shea C, Jansen PJ, "Formation of copper (I) from trace levels of copper (II) as an artifactual impurity in the HPLC analysis

of olanzapine", *J. Pharm. Biomed. Anal*., 125, 186-193 (2016). http://dx.doi.org/10.1016/j.jpba.2016.03.040

50. Allain L, **Baertschi SW**, Clapham D,* Foti C, Lantaff WM, Reed RA, Templeton AC,* and Tonnesen, HH, "Implications of In-Use Photostability: Proposed Guidance for Photostability Testing and Labeling to Support the Administration of Photosensitive Pharmaceutical Products. Part 3. Oral Drug Products", *J. Pharm. Sci.*, 105:5, 1586-1595 (2016). http://dx.doi.org/10.1002/jps.24396

49. Zhang T, and **Baertschi SW**, "Why Should We Care About Publishing?", *Org. Proc. Res. Dev*. 2015, 19, 559−560.

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47. Kleinman MH*, Elder D, Teasdale A, Mowery M, McKeown A, and **Baertschi SW***, "Strategies to Address Mutagenic Impurities Derived from Degradation in Drug Substances and Drug Products", *Org. Proc. Res. Dev*., 19:11, 1447-1457 (2015), DOI: 10.1021/acs.oprd.5b00091.

46. Strege M, Osborne L, Hetrick E, Dill, A, Jansen PJ, Draper JR, Montgomery RM, Buser J, Smitka T, Pack B, **Baertschi SW**, "Assessing the Risk of Formation of Potential Genotoxic Degradation Products in a Small-Molecule Kinase Inhibitor Drug Substance and Drug Product", *Org. Proc. Res. Dev*., 19:11, 1458-1464 (2015), DOI: 10.1021/acs.oprd.5b00112.

45. **Baertschi SW**, Clapham D,* Foti C, Kristensen S, Reed RA, Templeton AC,* Tonnesen HH. Implications of In-Use Photostability: Proposed Guidance for Photostability Testing and Labeling to Support the Administration of Photosensitive Pharmaceutical Products. Part 2. Topical Drug Products, *J. Pharm. Sci.*, 102:11, 3888-3899 (2015), DOI.10.1002/jps.24396 (2015).

44. Kleinman MH,* **Baertschi SW**, Alsante KM, Reid DL, Mowery MD, Shimanovich R, Foti C, Smith WK, Reynolds DW, Nefliu M, and Ott MA. "In Silico Prediction of Pharmaceutical Degradation Pathways: A Benchmarking Study", *Mol. Pharm*, 11, 4179-4188 (2014).

43. Alsante KM, Huynh-Ba K, Reed RA, **Baertschi SW**, Landis M, Furness S, Olsen BA, Mowery M, Russo K, Isler R, Stephenson GA, and Jansen PJ., "Recent Trends in Product Development and Regulatory Issues on Impurities in Active Pharmaceutical Ingredient (API) and Drug Products. Part 2. Safety Considerations of Impurities in Pharmaceutical

Products and Surveying the Impurity Landscape", *AAPS PharmSciTech*, 15:1, (2014) 237-251.

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41. Alsante KM, Huynh-Ba K, Reed RA, **Baertschi SW**, Landis M, Kleinman M, Foti C, Rao VM, Meers P, Abend A, Reynolds DW, and Joshi BK, "Recent Trends in Product Development and Regulatory Issues on Impurities in Active Pharmaceutical Ingredient (API) and Drug Products. Part 1: Predicting Degradation Related Impurities and Impurity Considerations for Pharmaceutical Dosage Forms ", *AAPS PharmSciTech*, 15(1), 198-212 (2013).

40. **Baertschi SW*,** Jansen PJ, Montgomery RM, Smith WK, Draper JR, Myers DP, Houghton PG, Sharp VS, Guisbert AL, Zhuang H, Watkins MA, and Harris TM, "Investigation of the Mechanism of Racemization of Litronesib in Aqueous Solution: Unexpected Base-Catalyzed Inversion of a Fully-Substituted Carbon Chiral Center", *J. Pharm. Sci*, 103:2797–2808 (2014).

39. Myers DP*, Hetrick EM, Zhongming L, Hadden CE, Bandy S, Kemp CAJ, Harris TM, **Baertschi SW**, "On-Column Nitrosation of Amines Observed in HPLC Impurity Separations Employing Ammonium Hydroxide and Acetonitrile as Mobile Phase", *J. Chrom. A.*, 1319, 57-64 (2013).

38. **Baertschi SW**,* Clapham D,* Foti C, Jansen PJ, Kristensen S, Reed RA, Templeton AC, Tonnesen HH. Implications of In-Use Photostability: Proposed Guidance for Photostability Testing and Labeling to Support the Administration of Photosensitive Pharmaceutical Products, Part 1: Drug Products Administered by Injection, *J. Pharm. Sci.* 102:11, 3888-3899 (2013).

37. **Baertschi SW**,* Pack BW, Hoaglund-Hyzer CS, and Nussbaum MA, "Assessing Mass Balance in Pharmaceutical Drug Products: New Insights into an Old Topic", *Trends in Analytical Chemistry*, 49, 126-136 (2013).

36. Dow LK,* Pack BW, Hansen MM, and **Baertschi SW**, "The Assessment of Impurities for Genotoxic Potential and Subsequent Control in Drug Substance and Drug Product", *J. Pharm. Sci.*,102(4), 1404-1418 (2013).

35. Raillard SP, Bercu J, **Baertschi SW,** and Riley CM, "Prediction of Drug Degradation Pathways Leading to Structural Alerts for Potential Genotoxic Impurities", *Org. Proc. Res. and Dev*., 14, 1015-1020 (2010).

34. **Baertschi SW**,* Alsante KM, and Tønnesen HH, "A Critical Assessment of the ICH Guideline on Photostability Testing of New Drug Substances and Products (Q1B): Recommendation for Revision", *J. Pharm. Sci.*, 99:7, 2934-2940 (2010).

33. Skibic MJ, King LA, Khan M, Fox PJ, Winger BE, and **Baertschi SW*** "Artifactual Formylation of Duloxetine Hydrochloride by Acetonitrile in the Presence of Titanium Dioxide and Ultrasonication: Implications for HPLC Method Development", *J. Pharm. Biomed. Anal*.,53, 432-439 (2010).

32. **Baertschi SW**,* Brunner H, Bunnell CA, Cooke GG, Diseroad B, Dorman DE, Jansen PJ, Kemp CAJ, Maple SR, McCune KA, and Speakman JL, "Isolation, Identification, and Synthesis of Two Degradation Products of Olanzapine (LY170053)", *J. Pharm. Sci.*, 97:2, 883-892 (2008).

31. **Baertschi SW*,** "Analytical Methodologies for Discovering and Profiling Degradation-Related Impurities", *Trends in Analytical Chemistry*, 25:8, 758-767 (2006).

30. Alsante KM,* Martin, L., and **Baertschi, SW*** "A Stress Testing Benchmarking Study", *Pharmaceutical Technology*, 27:2, pp. 60-72, February (2003).

28. Nussbaum MA,* **Baertschi SW**, and Jansen PJ, "Determination of Relative UV Response Factors by use of a Chemiluminescent Nitrogen-Specific HPLC Detector", *J. Pharm. Biomed. Anal.*, 27, 983-993 (2002).

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18. The Chemistry of Drug Degradation
19. The Role of "Mass Balance" in Pharmaceutical Stress Testing
20. Stress Testing: Frequently Asked Questions
21. Stress Testing: Relation to the Development Timeline
22. Stress Testing: Analytical Considerations
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38. Conference organizing committee and Symposia Chair, Science of Stability Conference, virtual conference, May 17-18 (2021).

37. Workshop organizing committee, Strategic Approaches to Develop Phase-Appropriate Organic Impurity Control Strategies, Impurities Community Group / AAPS, November 11-12 (2020).

36. Conference organizing committee and Chair, Science of Stability Conference, Amsterdam, Netherlands, Oct 14-15 (2019).

35. Conference organizing committee and Chair, Science of Stability Conference, Boston, MA, Oct 21-23 (2018).

34. Conference organizing committee and Conference Chair, Science of Stability Conference, Dublin, Ireland, Oct 3-5 (2017).

33. Conference organizing committee, AAPS Stability Workshop, Hilton-Rockville, Rockville, MD (2017)

32. Conference organizing committee, Science of Stability Conference, Newark, NJ, Sept 25-27 (2016)

31. Conference organizing committee, AAPS Stability Workshop, USP Headquarters, Rockville, MD April 4-5, 2016.

30. Conference organizing committee, Photostability 2015, Oct 5-7, Loughborough, UK, 2015.

29. Co-Chair and organizing committee, Science of Stability Conference, Oct 12-14, Mashantucket, CT, 2015.

28. Steering Committee Member, Conference on Small Molecule Science (CoSMoS), Williamsburg, VA, August 2014.

27. Steering Committee Member for AAPS Workshop on "Atypical Impurities", Nov 9-10, San Antonio, TX, 2013.

26. Steering Committee Member (Forced Degradation Track), Conference on Small Molecule Science (CoSMoS), LaJolla, CA, August 2013.

25. Co-Organizer for Predicting and Monitoring Impurities in the API and Drug Products: Product Development and Regulatory Issues, AAPS Workshop, Oct 13-14, McCormick Place, Chicago, IL, 2012.

24. Steering Committee Member (Forced Degradation Track), Conference on Small Molecule Science (CoSMoS), Providence, RI, August 2012.

23. AAPS Physical Stability Symposium at AAPS Annual Meeting, Steering Committee Member, Washington, DC, October 27, 2011.

22. AAPS APQ Stability Meeting Workshop at AAPS Annual Meeting – Steering Committee Member, Washington, DC, October 23-24, 2011.

21. AAPS APQ Stability Meeting Workshop at AAPS Annual Meeting – Steering Committee Member, Washington, DC, October 23-24, 2011.

20. Steering Committee Member, Conference on Small Molecule Science (CoSMoS), Co-Chair Forced Degradation Track, UNC-Chapel Hill, Aug 1-3, 2011.

19. Steering committee member and Co-Chair for "Informa Life Sciences 5th Annual Conference on Forced Degradation", London, UK, Jan 25-26, 2011.

18. Steering Committee Member, "Impurities, Degradation Products, and Forced Degradation Studies for APIs and Drug Products, USP Workshop, Sao Paulo, Brazil, May 19-20, 2011.

17. Co-organizer / co-chair for "6th Annual conference on Forced Degradation", hosted by the Institute for International Research, Philadelphia, PA, March 15-16, 2010

16. Steering committee member, "AAPS Workshop on Current Trends in Stability – Challenges with Today's New Products", co-sponsored with PhRMA, National Harbor, MD, Sept 24-25, 2009.

15. Organizing committee member for conference on Photostability: "*Photostability 08: 7th International Conference on the Photostability of Drug Substances and Drug Products*, hosted by the Association of Pharmaceutical Scientists of Great Britain, London, UK, Oct 1-3, 2008.

14. Organizer / co-chair for an AAPS workshop on Degradation, Nov 10, 2007, AAPS Annual Meeting, San Diego, CA.

13. Steering committee member for an AAPS workshop on Stability, Bethesda, MD, Sept 10-12, 2007.

12. Steering committee member and co-chair for a conference on Stress Testing: "4th Annual conference on Forced Degradation: Best Practices for the Pharmaceutical Industry", hosted by the Institute for International Research, Las Vegas, NV, Jan 22-24, 2007.

11. Steering committee member and co-chair for a conference on Photostability: *Photostability '06,* joint meeting with Annual Meeting of the American Society for Photobiology, Rio Grande, Puerto Rico, July 8-13, 2006.

10. Co-organizer / co-chair for a conference on Stress Testing: "3rd Annual conference on Forced Degradation: Best Practices for the Pharmaceutical Industry", hosted by the Institute for International Research, Short Hills, NJ, Feb 15-17, 2006.

9. Organizing committee member and chair of "5th Annual Impurities Summit", hosted by the Institute for International Research, Princeton, NJ, May 16-18, 2005.

8. Organizing committee member / co-chair of conference on Stress Testing: "Forced Degradation: Best Practices for the Pharmaceutical Industry", 2nd Annual conference, hosted by the Institute for International Research, Washington, DC, Feb 15-16, 2005.

7. Co-organizer for an AAPS "Sunrise School" symposium on the "The Chemistry of Drug Degradation", American Association of Pharmaceutical Scientists National Meeting, Baltimore, MD, October 2004.

6. Organizing committee member / chair for a conference on Oxidative Degradation: "Oxidative Degradation and Stabilization Conference", presented by the Institute for International Research, Princeton, NJ, July 20-21, 2004.

5. Organizing committee member for conference on Photostability: "*Photostability 04: 5th International Conference on the Photostability of Drug Substances and Drug Products*, London, UK, June 16-20, 2004.

4. Co-organizer/co-chair for a conference on Stress Testing: "Forced Degradation: Best Practices for the Pharmaceutical Industry", presented by Institute for International Research, Princeton, NJ, February 24-25, 2004.

3. Organizing committee member / co-chair for a conference on Photostability: *Photostability 01: 4th International Conference on the Photostability of Drug Substances and Drug Products*, Research Triangle Park, NC, July 16-19, 2001.

2. Co-organizer/co-chair for a conference on Photostability: *Photostability '99,* joint meeting with 27th Annual Meeting of the American Society for Photobiology, Washington, DC, July 10-15, 1999

1. Co-organizer/co-chair for a conference on Photostability: *Photostability, a 1997 Update; Scientific, Regulatory, and Practical Issues*, AAI Seminar Series, Arlington, VA, February 24-25, 1997.

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141. **Baertschi SW**,* "N-Nitrosamines: Chemistry and Risk Assessment in Formulated Products", virtual presentation at the 2nd Annual Nitrosamines Impurities Forum, Informa Market / CPhI Conference, Sept. 28, (2021).

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92. Dill A,* **Baertschi SW,*** Kramer T, and Sperry DC "Predicting the Degradation Rate as a Function of Drug Load in Solid-State Products", presented at the Conference on Small Molecule Science, Williamsburg, VA, Aug 10 (2014).

91. **Baertschi SW**,* "Lean Strategies for Conducting Forced Degradation Studies and Downstream Implications", AAPS Symposium on Stability, AAPS Annual Meeting, Nov 14, San Antonio, TX (2013).

90. **Baertschi SW**,* "Unexpected Stability Issues Related to Unexpected Impurities from Excipients", AAPS Atypical Impurities Workshop, Nov 9-10, San Antonio, TX (2013).

89. **Baertschi SW**,* "Lean Stability: Forced Degradation, Real Time Stability, and Analytical Methodology", invited oral presentation at a workshop on Stability for ANVISA, ANVISA Headquarters, Brasilia, Brazil, Oct 2-3 (2013).

88. **Baertschi SW**,* "Overview of Pharmaceutical Photostability Testing", invited oral presentation at a workshop on Stability for ANVISA, ANVISA Headquarters, Brasilia, Brazil, Oct 2-3 (2013).

87. **Baertschi SW**,* McFarland AD, Stephenson GA, "Physical Stability Issues in Pharmaceutical Development", invited oral presentation at a workshop on Stability for ANVISA, ANVISA Headquarters, Brasilia, Brazil, Oct 2-3 (2013).

86. **Baertschi SW,*** "Forced Degradation, Real Time Stability, and Analytical Methodology", invited oral presentation at the US-FDA, Office of Generic Drugs Training Seminar, Sept 18 (2013).

85. Dow L,* Pack B, **Baertschi SW**, Hansen M, Page TJ, "The assessment of impurities for genotoxic potential and subsequent control in drug substance and drug product" – oral presentation at 5th Annual Genotoxic Impurities conference, Informa Life Sciences (Berlin), June (2013).

84. Kopach ME*, **Baertschi SW**, Kobierski ME, Nguyen Hawk MK, Dione A, Williamson ML, Hoaglund-Hyzer C, and Jansen PJ, "Understanding the pharmaceutically-relevant Maillard reaction", invited presentation at Drug Discovery & World Congress, June 3 (2013).

83. **Baertschi, S.W.*** and Mowery, M. "ICH M7 Guidance on Genotoxic Impurities: Implications for the Analytical Laboratory", invited oral presentation at the 52nd Annual Pharmaceutical Analysis /, Land O'Lakes Conference, Aug (2012).

82. Myers DP*, Liang Z, Hetrick E, Hadden C, Bandy S, Harris TM, and **Baertschi, SW**, "On-column N-nitrosation of amines observed in high pH HPLC impurity separations", invited oral presentation at Eastern Analytical Symposium, Somerset, NJ, Nov 12-15 (2012).

81. Foti, C*; Alsante, K; **Baertschi, S.W**. "The Chemistry of Drug Degradation", 1-day workshop, Eastern Analytical Symposium, Somerset, NJ, Nov 12-15 (2012).

80. Mowery, MA* and **Baertschi, S.W.** "Potential Genotoxic Degradants: ICH Working Group Update", invited oral presentation at the AAPS Annual Meeting Preconference Workshop on *Predicting and Monitoring Impurities in API and Drug Products,* Oct 13-14, 2012.

79. **Baertschi, S.W.***, Fundamentals of Predicting Oxidative Impurities", invited oral presentation at the AAPS Annual Meeting Preconference Workshop on *Predicting and Monitoring Impurities in API and Drug Products,* Oct 13-14, 2012.

78. **Baertschi, S.W.***, "Revisiting Old Concepts: New Insights into the Concept of Mass Balance in Drug Products", invited oral presentation at the AAPS Annual Meeting Preconference Workshop on *Predicting and Monitoring Impurities in API and Drug Products,* Oct 13-14, 2012.

77. Kramer TT, Ritcher DW, Jansen PJ, Risley DS, Sharp V.S, and **Baertschi SW***, "New Ways to Visualize the Results of Forced Degradation Studies", invited oral presentation at Conference on Small Molecule Science, Providence, RI, Sept 10, 2012.

76. Alsante, K*, **Baertschi, S.W.,** and Foti, C., "Reviewing Advances in Knowledge of Drug Degradation Chemistry", Forced Degradation for Pharmaceuticals, Informa Life Sciences, London, UK, Jan 18-19, 2012.

75. **Baertschi, S.W.,*** Dow, L., Hansen, M., and Pack, B., "Stress Testing and Degradation-Derived Genotoxic Impurities: Scientific, Practical, and Regulatory Considerations", Challenges and Opportunities for the Control of Genotoxic Impurities Symposium, AAPS Annual Meeting, Washington, DC, Oct 26, 2011.

74. McFarland, A.D.,* Stephenson, G.A., and **Baertschi, S.W.*,** "Challenges in the Analytical Characterization of Physical Stability Issues", Predicting and Managing Stability Programs with Physical Stability Issues Symposium, AAPS Annual Meeting, Washington, DC, Oct 26, 2011.

73. Skibic, M.J.*, King, L.A., Khan, M., Fox, P.J., Winger, B.E., and **Baertschi, S.W.,** "Artifactual Formylation of the Secondary Amine of Duloxetine Hydrochloride by Acetonitrile in the Presence of Titanium Dioxide: Implications for HPLC Method Development", AAPS Stability Workshop, Washington, DC, October 22-23, 2011.

72. **Baertschi, S.W.*,** Alsante, K.M., and Tonnesen, H.H., "ICH Q1B Photostability Guideline: Time for a Revision?", AAPS Stability Workshop, Washington, DC, October 22-23, 2011.

71. Skibic, M.J.*, King, L.A., Khan, M., Fox, P.J., Winger, B.E., and **Baertschi, S.W.,** "Artifactual Formylation of the Secondary Amine of Duloxetine Hydrochloride by Acetonitrile in the Presence of Titanium Dioxide: Implications for HPLC Method Development", Conference on Small Molecule Science, UNC-Chapel Hill, Aug 2, 2011.

70. Jansen, P.J.*, Williamson, M., Hoaglund-Hyzer, C., Kopach, M., and **Baertschi, S.W**. "Drug-Excipient Compatibility: Investigation of the Mechanism of N-Formylation of Amines by Reducing Sugars", Conference on Small Molecule Science, UNC-Chapel Hill, Aug 2, 2011.

69. **Baertschi, S.W.***, Elder, D., Kleinman, M. McKeown, A., Mowery, M., Norwood, D., Teasdale, A., Dow, L., and Pack, B. "Stress Testing and Degradation-Derived Genotoxic

Impurities: Scientific, Practical, and Regulatory Considerations", Conference on Small Molecule Science, UNC-Chapel Hill, Aug 2, 2011.

68. Pack, B.W.,* Hetrick E., Dow L., **Baertschi, S.W**., Hansen, M. "Overcoming the hurdles to rapid and accurate prediction of shelf-life and degradation profiles", invited oral presentation at "Impurities", sponsored by Informa Life Sciences, Prague, Czech Republic, Sept. 15, 2011.

67. **Baertschi, S.W.*,** "Fundamentals of Photochemistry and Photostability Testing", USP Workshop, Sao Paulo, Brazil, May 19-20, 2011.

66. **Baertschi, S.W**.*, "Strategies for Investigation and Control of Degradation-Related Impurities", USP Workshop, Sao Paulo, Brazil, May 19-20, 2011.

65. **Baertschi, S.W**.*, Jansen, P.J., Campbell, B.M., and Draper, J.R. "Implementing Automation in the Pharmaceutical Development Laboratory: The Symyx Automated Forced Degradation System", Symyx Global Symposium, Prague, Czech Republic, May 20, 2008.

64. **Baertschi, S.W.,*** "The Foundational Aspects of Predicting Drug Degradation", invited oral presentation at the DIA / AAPS co-sponsored CMC Workshop: Translating Science into Successful Regulatory Submissions, Washington, DC, Feb 7-9, 2011.

63. **Baertschi, S.W.*,** and Jansen, Patrick J. "Degradation or Artifact: Stress Testing Brain Teasers", invited oral presentation at the"5th Annual Conference on Forced Degradation", Informa Life Sciences, London, UK, Jan 25-26, 2011.

62. **Baertschi, S.W.*,** "Stress Testing: Predictive or Overkill", invited oral presentation at the"5th Annual Conference on Forced Degradation", Informa Life Sciences, London, UK, Jan 25-26, 2011.

61. **Baertschi, S.W.*,** "Predicting Drug Degradation", invited oral presentation at the AAPS Workshop on Stability Testing in Pharmaceutical Development, New Orleans, LA, November 14, 2010.

60. **Baertschi, S.W.***, Raillard, S., Bercu, J., and Riley, C.M. "Prediction of Drug Degradation Pathways Leading to Structural Alerts for Potential Genotoxic Impurities", invited oral presentation, Informa Life Sciences Conference on Genotoxic Impurities, June 29, Zurich, Switzerland, 2010.

59. **Baertschi, S.W**.* "Patterns and Pathways: Using Chemistry to Guide the Characterization of Drug Degradation Products", invited oral presentation, 6th Annual Forced Degradation Forum, Institute for International Research, Philadelphia, PA, March 15-16, 2010.

58. **Baertschi, S.W.*** "Destroying Drugs for the Purpose of Bringing Them to Market", and "Working as a Scientist in the Pharmaceutical Industry", Vanderbilt University, Center in Molecular Toxicology Seminar Series, Nashville, TN, Feb 24, 2010.

57. **Baertschi, S.W.*** "Patterns and Pathways: Using Chemistry to Guide the Characterization of Drug Products", invited oral presentation, Eastern Analytical Symposium, Somerset, NJ, November 18, 2009.

56. Alsante, K.M.*, and **Baertschi, S.W.*** "The Chemistry of Drug Degradation", One Day Short Course, Eastern Analytical Symposium, Somerset, NJ, November 17, 2009.

55. **Baertschi, S.W.*,** invited oral presentation, "Predicting Drug Degradation via in cerebro Knowledge: A Fresh Look at Degradation Pathways", AAPS Stability Workshop, National Harbor, MD, Sept 24-25, 2009.

54. **Baertschi, S.W.*,** Draper, J.R., Jansen, P.J., and Smith, William, K. "Oxidative Susceptibility Testing: Rapid, Comprehensive, Screening Techniques", invited oral presentation, 3rd Annual Conference on Forced Degradation, Informa Health Sciences, Brussels, Belgium, Jan 29-30, 2009.

53. Alsante, K.M.,* and **Baertschi, S.W.** "Chemistry-Guided Approach to Degradation Studies", oral presentation, 3rd Annual Conference on Forced Degradation, Informa Health Sciences, Brussels, Belgium, Jan 29-30, 2009.

52. **Baertschi, S.W.*,** and Alsante, K.M.* "The Chemistry of Drug Degradation", 1-Day Organic Master Class, 3rd Annual Conference on Forced Degradation, Informa Health Sciences, Brussels, Belgium, Jan 31, 2009.

51. **Baertschi, S.W.***, "Forced Degradation Studies and Genotoxic Impurities: Scientific and Regulatory Issues", invited oral presentation, Genotoxic Impurities Conference, hosted by the Institute for International Research, Philadelphia, PA, Dec 8-9, 2008.

50. **Baertschi, S.W.*** "Fundamentals of Photochemistry and Photostability Testing", invited oral presentation, 1-Day short course on Photostability, Photostability 2008, hosted by the Association of Pharmaceutical Scientists of Great Britain, London, UK, Oct 1, 2008.

49. Smith, W.K., Jansen, P.J., Kiehl, D.E., Behme, R.J., and **Baertschi, S.W.*** "Drug Photodegradation in the Solid State: Unexpected Photochemistry Observed in a Lyophilized Product", oral presentation at the Annual Meeting of the American Society for Photobiology, Burlingame, CA, June 2008.

48. **Baertschi, S.W.*,** Draper, J.R., Jansen, P.J., and Smith, William, K. "Oxidative Susceptibility Testing: Rapid, Comprehensive, Screening Techniques", invited oral presentation, 2nd Annual Conference on Forced Degradation, Informa Health Sciences, Amsterdam, Netherlands, Jan 31, 2008.

47. **Baertschi, S.W.*,** and Alsante, K.M.* "Fundamentals of Photochemistry and Photostability Testing", Organic Master Class, 2nd Annual Conference on Forced Degradation, Informa Health Sciences, Amsterdam, Netherlands, Jan 31, 2008.

46. **Baertschi, S.W.*,** and Alsante, K.M.* "The Chemistry of Drug Degradation", 1-Day Organic Master Class, 2nd Annual Conference on Forced Degradation, Informa Health Sciences, Amsterdam, Netherlands, Jan 31, 2008.

45. **Baertschi, S.W**.*, Campbell, B.M., Draper, J.R., and Jansen, P.J. "Automating the Analytical Laboratory: Is it Worth the Effort?", invited oral presentation at the 4th Annual Forced Degradation conference, hosted by the International Institute for Research, Las Vegas, NV, Jan 22-24, 2007.

44. Toltl, N*, **Baertschi, SW**, Wozniak TJ, and Olsen, BA,* "Artifact Peaks in HPLC Impurity Analysis Caused by Trace Levels of Copper", poster presentation at HPLC, San Francisco, CA, 2006.

43. **Baertschi, S.W.*** "Destroying Drugs for the Purpose of Bringing Them to Market: Pharmaceutical Stress Testing", invited oral presentations at the University of Wisconsin-Madison and UW-Milwaukee, Sept. 28-29, 2006.

42. **Baertschi, S.W.***, Campbell, B.M., Draper, J.R., and Jansen, P.J., "Implementing Automation in the Pharmaceutical Development Laboratory: The Symyx Automated Forced Degradation System," Invited oral presentation at the Symyx User Group Meeting, Annapolis, MD, June 2006.

41. **Baertschi, S.W**.*, Draper, J.R., Jansen, P.J., and Smith, W.K., "Oxidative Susceptibility Testing: Rapid, Comprehensive Screening Techniques", Invited oral presentation at the

3rd Annual Forced Degradation conference, Institute for International Research, Short Hills, NJ, Feb. 2006.

40. **Baertschi, S.W.*** "Destroying Drugs for the Purpose of Bringing Them to Market: Pharmaceutical Stress Testing", invited oral presentation at the University of Oslo, Depts of Pharmaceutics and Chemistry, Oslo, Norway, November 2005.

39. **Baertschi, S.W**.* "Destroying Drugs for the Purpose of Bringing Them to Market: Pharmaceutical Stress Testing", Short Course at Lehigh University, Bethlehem, PA, April 10, 2005.

38. **Baertschi, S.W.*** "Forced Degradation and Its Relationship to Real Time Drug Product Stability", APQ Open Forum, AAPS Annual Meeting, Nashville, TN, Nov 2005.

37. **Baertschi, S.W.**,* Campbell, B.M., Draper, J.R., Jansen, P.J., Maxwell, L.N., and Smith, W.K "Uncovering New Impurities by Investigating Mass Balance Issues Observed During Stress Testing Studies", invited oral presentation, *5th Annual Impurities Summit*, Institute for International Research, Princeton, NJ, May 18, 2005.

36. **Baertschi, S.W.,*** Campbell, B.M., Draper, J.R., Jansen, P.J., Maxwell, L.N., and Smith, W.K ". "Strategies for Assessing Mass Balance in Partially-Degraded Samples", invited oral presentation "3rd Annual Forced Degradation Conference: Best Practices for the Pharmaceutical Industry, Institute for International Research, Washington, DC, Feb. 15, 2004.

35. **Baertschi, S.W.**,* and Alsante, K.M.* "The Chemistry of Drug Degradation", oral presentation at the AAPS Sunrise School, AAPS National Meeting, Baltimore, MD, November 9, 2004.

34. **Baertschi, S.W.,*** Draper, J.R., Jansen, P.J., Maxwell, L.N., and Smith, W.K. "Oxidative Susceptibility Testing: Rapid, Comprehensive Screening Techniques", Oxidative Degradation and Stabilization Conference, Institute for International Research, Princeton, NJ, July 20-21, 2004.

33. **Baertschi, S.W.*** "Strategies for Investigation and Control of Degradation-Related Impurities", invited presentation at the FDA Impurities Workshop, Gaithersburg, MD, March 22 (2004).

32. **Baertschi, S.W.*** "Pharmaceutical Photostability: Sample Presentation", invited presentation as part of the short course on Pharmaceutical Photostability, Photostability

04: 5th International Conference on the Photostability of Drug Substances and Drug Products, London, UK, July 14-16 (2004).

31. **Baertschi, S.W.**,* Jansen, P.J., Maxwell, L.N., and Smith, W.K. "Strategies for Investigation and Control of Degradation-Related Impurities", invited oral presentation, ACS Central Eastern Regional Meeting, Indianapolis, IN, June 2-4 (2004).

30. **Baertschi, S.W.*** and K.M. Alsante,* "The Chemistry of Drug Degradation", oral presentation, Forced Degradation: Best Practices for the Pharmaceutical Industry, Institute for International Research, Princeton, NJ, Feb. 24-25 (2004).

29. **Baertschi, S.W.,***, Nussbaum, M.A., Smith, W.K., and Jansen, P.J. "Strategies for Assessing Mass Balance in Partially-Degraded Samples", invited oral presentation, AAI Stability Seminar, Wilmington, NC, March 26-27, 2003.

28. **Baertschi, S.W.**,* Nussbaum, M.A., Smith, W.K., and Jansen, P.J., "Strategies for Assessing Mass Balance in Partially-Degraded Samples", invited oral presentation, *Detecting, Identifying, and Quantitating Impurities*, Institute for International Research, Princeton, NJ, May 20-21, 2002.

27. **Baertschi, S.W.*** "Destroying Drugs for the Purpose of Bringing Them to Market: Pharmaceutical Stress Testing", invited oral presentation at the Thomas L. Harris Symposium, Departments of Chemistry and the Center for Molecular Toxicology, Vanderbilt University, Nashville, TN, Sept 7, 2001.

26. **Baertschi, S.W.**,* "ICH Option 1 and Option 2 Sources: Potential for Different Photodegradation Pathways", oral presentation, Photostability 01: 4th International Conference on the Photostability of Drug Substances and Drug Products, Research Triangle Park, NC, July 16-19 (2001).

25. **Baertschi, S.W.***, "Pharmaceutical photostability testing: sample presentation", invited oral presentation, Photostability 01: 4th International Conference on the Photostability of Drug Substances and Drug Products, Research Triangle Park, NC, July 16-19, 2001.

24. **Baertschi, S.W.***, "Strategies for Investigation and Control of Process-Related Impurities", invited oral presentation, *Detecting, Identifying, and Quantitating Impurities*, Institute for International Research, Philadelphia, PA, March 27-28, 2001.

23. **Baertschi, S.W.***, "Current Trends in Photostability 1 – Practical Considerations in Designing and Implementing Photostability Studies", invited oral presentation, *Stability of*

Pharmaceuticals: Current Issues, Practices, and Technologies, University of Wisconsin-Madison Seminar Series, Costa Mesa, CA, November 13-14, 2000.

22. Allen, J.M.,* Allen S.A., Dreiman, J., and **Baertschi, S.W.** "2-Nitrobenzaldehyde: A Convenient UV-A and UV-B Chemical Actinometer for Drug Photostability Testing", oral presentation at " *Photostability '99*, joint meeting with 27th Annual Meeting of the American Society for Photobiology, Washington, DC, July 10-15, 1999.

21. **Baertschi, S.W.***, Kinney H.D., Snider, B.G.* "Issues in Evaluating the 'In-Use' Photostability of Transdermal Patches", oral presentation, *Photostability '99,* joint meeting with 27th Annual Meeting of the American Society for Photobiology, Washington, DC, July 10-15, 1999.

20. **Baertschi, S.W.*** "Designing and Implementing Photostability Studies in Alignment with ICH Guidelines", invited oral presentation, *Statistical Methods for Determining and Justifying Your Specifications and Shelf-Life", Institute for International Research*, Bethesda, MD, Sept. 22-24, 1999.

19. **Baertschi, S.W.*** "Practical Aspects of Pharmaceutical Photostability Testing", *Photostability '99*, invited oral presentation, joint meeting with 27th Annual Meeting of the American Society for Photobiology, Washington, DC, July 10-15, 1999.

18. **Baertschi, S.W.*** "Designing and Implementing ICH-Compliant Photostability Studies", invited oral presentation, Pharmaceutical Stability: Statistical Applications, Regulatory Updates, and Current Industry Practices", AAI Seminar Series, East Brunswick, NJ, February 22-23, 1999.

17. **Baertschi, S.W.*** "Designing and Implementing Photostability Studies in Alignment with ICH Guidelines", invited oral presentation, Preparing for Changing Paradigms in Pharmaceutical Stability Programs, Institute for International Research, Philadelphia, PA, September 16, 1998.

16. **Baertschi, S.W.*** "Designing and Implementing Photostability Studies in Alignment with ICH Guidelines", invited oral presentation, Barnett-Parexel's Conference on Stability Testing, Washington, DC, September 14, 1998.

15. **Baertschi, S.W.*** "Pharmaceutical Stress Testing", invited oral presentation at Indiana State University-Terre Haute, Terre Haute, IN, March 17, 1998.

14. **Baertschi, S.W.*** "Destroying Drugs for the Purpose of Bringing Them to Market", invited oral presentation at Rocky Mountain College, Billings, MT, Feb. 26, 1998.

13. Eckstein, M.,* **Baertschi, S.**, Jansen, P., Maple, S., and Wozniak T., "A light-catalyzed formation of formaldehyde in a drug product", AAPS Meeting, Boston, MA, Nov. 2, 1997.

12. **Baertschi, S.W.*** "Photostability Testing: Practical Issues Related to Sample Exposure", invited oral presentation, Photostability, a 1997 Update; Scientific, Regulatory, and Practical Issues, AAI Seminar Series, Arlington, VA, February 24-25, 1997.

11. **Baertschi, S.W.*** "The Role of Stress Testing in Method Development and Validation", invited oral presentation, 1996 Calibration and Validation Symposium, Etobicoke, Ontario, October 2, 1996.

10. **Baertschi, S.W.*** "The Role of Stress Testing in Pharmaceutical Product Development", invited lecture, AAPS Midwest Regional Meeting, Chicago, IL, May 20, 1996.

9. **Baertschi, S.W.*** "Destroying Drugs for the Purpose of Bringing Them to Market: Pharmaceutical Stress Testing", invited lecture, Indiana University-Purdue University at Indianapolis (IUPUI), February 21, 1996.

8. **Baertschi, S.W.**,* Dorman, D.E., Occolowitz, J.L., Collins, M.W., and Lorenz, L.J. "Characterizing Drug Degradation Pathways Through Stress Testing: The Complex Degradation Chemistry of Cefaclor", presented at the American Association of Pharmaceutical Sciences (AAPS) Meeting, Orlando, FL, Nov., 1993.

7. Olsen, B.A.,* **Baertschi, S.W.**, and Riggin, R.M. "Multidimensional Evaluation of Impurity Profiles for Generic Cephalexin and Cefaclor Antibiotics", presented at the American Chemical Society National Meeting in Washington, D.C., August, 1992.

6. Gopalakrishnan, S.,* **Baertschi, S.W.**, Raney, K.D., Stone, M.P., and Harris, T.M. "Characterization of Aflatoxin B_1-Oligonucleotide Adducts", Sixth Conversation in Biomolecular Stereodynamics, State University of New York at Albany, 1989, 6.

5. Brash, A.R.,* **Baertschi, S.W.**, and Harris, T.M. "Non-cyclooxygenase Prostaglandin Biosynthesis: Formation of PGA_3 Isomers via an Allene Oxide", Biological Oxidation Systems [Proc. Symp.] 2, pp. 683-693 (1990)

4. Stone, M.P.,* Harris, T.M., **Baertschi, S.W.**, Byrd, S., Gopalakrishnan, S., and Raney K.D. "Equilibrium and Covalent Binding of Aflatoxins with DNA", Biophysical Journal, 33rd annual meeting, 1989, **55**, 240a.

3. Harris, T.M.,* **Baertschi, S.W.**, Raney, K.D., Gopalakrishnan, S., Byrd, S., and Stone, M.P. "Preparation and Reactions of Aflatoxin B_1-Epoxide; the Ultimate Carcinogen of Aflatoxin B_1", Abstracts of the 40th American Chemical Society Southeast Regional Meeting, Atlanta, GA, November, 1988.

2. **Baertschi, S.W.**,* Harris, T.M., Seibert, K., Wendelborn, D.F., and Roberts, L.J. II "Structure Elucidation of Prostaglandin F_2 Isomers Arising by In Vitro Reduction of Prostaglandin D_2 ", presented at the Southeastern Conference on Magnetic Resonance, 1986, Nashville, TN.

1. **Baertschi, S.W.**,* Harris, T.M., and Brash, A.R. "Determination of the Relative Stereochemistry of the Alkyl Side-Chains of Prostanoid Compounds by ^{1}H-NMR", presented at the Southeastern Conference on Magnetic Resonance, 1986, Nashville, TN.

*Presenter(s)

INTERNAL REPORTS

- Authored well over 100 internal technical reports, primarily dealing with identification of degradation and photodegradation products and pathways, low-level impurities, and chemical and physical stability-related problems in both drug substances and drug products.
- Official scientific reviewer for well over 200 additional internal technical reports.

REGULATORY DOCUMENTS

Authored or co-authored Stress Degradation and Confirmation of Structure sections of approx. 15 NDA/EU Dossier global regulatory submissions, including Ceclor (cefaclor), Zyprexa (olanzapine), Evista (raloxifene), Lorabid (loracarbef), Strattera (atomoxetine), Cialis (tadalafil), Cymbalta (duloxetine), Alimta (pemetrexed), Zyprexa RAIM (olanzapine rapid acting intramuscular), Arxxant (ruboxistaurin hydrochloride), Effient (prasugrel), Arzoxifene, several Japan regulatory NDA submissions, and over two dozen Confirmation of Structure sections for IND / CTA regulatory submissions. Have authored numerous responses to regulatory questions from various regulatory agencies worldwide.

LEGAL / PATENT DISPUTES

- 2021 – present. Retained by GreenbergTraurig as an Expert witness for Teva re: Valsartan, Losartan, and Irbesartan Products Liability Litigation, Case No. 1:19-md-2875-RBK.
- 2021 – present. Retained by Devlin Law Firm LLC as an Expert Witness for *Exela Pharma Sciences, LLC v. Eton Pharmaceuticals, Inc.*, District of Delaware, Civil Action No. 20-cv-0365-MN. Deposed on June 11, 2021, certification no. 084-003435.
- 2019, Retained as Expert consultant for Wilson, Sonsini, Goodrich & Rosati for Mylan Laboratories re: Teva Pharmaceuticals International GmbH et al. v. Mylan Laboratories Ltd, Civil Action No. 1:17-cv-01790-GMS (D.Del.).
- 2016-2018, Expert Witness role, including Expert Report and Deposition, for Joint Defense Team (11 legal firms across the US, hired by Wilson, Sonsini, Goodrich & Rosati, Palo Alto, CA) vs Takeda and AZ in patent dispute, Consolidated Civil Case No 3:15-cv-03375-FLW-DEA.

EXHIBIT B

GT GreenbergTraurig

In re: Valsartan, Losartan, and Irbesartan Products Liability Litigation
Case No. 19-2875

STEVEN W. BAERTSCHI, PH.D., FAAPS
LIST OF MATERIALS CONSIDERED

REVIEW MATERIALS PROVIDED	BATES NOS.
MDL PLEADINGS AND GENERAL DOCUMENTS	
2019.06.17 - 0122 - Amended Complaint - Master Personal Injury Complaint	N/A
2019.06.17 - 0123 - Amended Medical Monitoring	N/A
2020.03.13 - 0398 - 2nd Amended Economic Loss Class Action Complaint	N/A
2021.11.01 – 3rd Amended Economic Loss Class Action Complaint	N/A
2020.12.31 - 0706 - Plaintiff Cancer Disclosure Type	N/A
Plaintiffs' Memorandum ISO Motion for Class Cert – EL w/ Exhibits	N/A
EXPERT REPORTS (with exhibits)	
Plaintiffs' Expert Reports (with exhibits)	
2021.11.07 – Declaration of John L. Quick	N/A
2021.07.06 – Report of Dipak Panigrahy	N/A
2021.07.07 – Report of David Madigan	N/A
2021.11.04 - Declaration of Ron Najafi, Ph.D.	N/A
2021.11.09 – Report of Kali Panagos, Pharm.D., R. Ph.	N/A
2021.11.10 - Report of Edward H. Kaplan, M.D.	N/A
2021.11.10 – Declaration of Rena Conti, Ph.D.	N/A
2021.11.10 – Declaration of Laura R. Craft	N/A
2021.11.10 – Report of Zirui Song, M.D., Ph.D.	N/A
2021.07.06 – Report of Mahyar Etminan	N/A
2021.07.06 – Report of Dipak Panigrahy	N/A
2021.07.06 – Report of Stephen S. Hecht	N/A
2021.07.06 – Report of Stephen M. Lagana	N/A
2021.07.06 – Report of David Madigan	N/A
TEVA WITNESSES DEPOSITIONS	
Elizabeth Gray – 02.26.2021 - Transcript	N/A
1 - Amended Notice of Deposition	N/A
2 - Supplement CBE-30 9/9/14	TEVA-MDL2875-00001886
3 - Supplement CBE-30 1/9/15	TEVA-MDL2875-00013107
4 - ANDA Approval Rescission	TEVA-MDL2875-00261415
5 - E-mail Thread 7/3/18 Subject, Field Alert Update Valsartan	TEVA-MDL2875-00063799-03
6 - E-mail Thread 8/3/18 Subject, ANDA 091519 Correspondence NDMA	TEVA-MDL2875-00004494-99
7 - E-mail Thread 9/6/18 Subject, ANDA 200435 NDMA Letter	TEVA-MDL2875-00154157-61
8 - E-mail Thread 10/9/18 Subject, FDA Valsartan Results	TEVA-MDL2875-00154181-82
9 - E-mail Thread 10/31/18 Subject, U.S. Samples for Testing	TEVA-MDL2875-00154186-93

GT GreenbergTraurig

REVIEW MATERIALS PROVIDED	BATES NOS.
10 - E-mail Thread 11/14/18 Subject, U.S. Samples for Testing	TEVA-MDL2875-00537590-604
11 - E-mail Thread 2/15/19 Subject, ANDA 091129 IR Letter	TEVA-MDL2875-00395567-74
12 - E-mail Thread 3/29/19 Subject, ANDA 091129 IR Letter	TEVA-MDL2875-00395653-60
13 - E-mail Thread 10/25/18 Subject, NDEA Possible Other Impurity	TEVA-MDL2875-00137965-70
14 - E-mail Thread 3/6/19 Subject, Nitrosamine General Advice Letter 3.1.19	TEVA-MDL2875-00154434-35
15 - Response to FDA Request for Information ANDA 091519	TEVA-MDL2875-00765609
16 - E-mail Thread 7/18/19 Subject, Valsartan Reports	TEVA-MDL2875-00693421, 24
17 - Letter, 8/20/18 Subject, Voluntary Recall	TEVA-MDL2875-00065014-16
18 - Letter, 8/8/19 Subject, Amlodipine and Valsartan	TEVA-MDL2875-00015129
19 - E-mail Thread 12/18/19 Subject, Emailing Valsartan Recall 72018 13th Monthly Update	TEVA-MDL2875-00095922-23
20 - E-mail Thread 1/4/19 Subject, Destruction Request Valsartan	TEVA-MDL2875-00014826-27
21 - E-mail Thread 4/1/19 Subject, Destruction Request Valsartan	TEVA-MDL2875-00014763
22 - E-mail Thread 11/14/18 Subject, GI Entries	TEVA-MDL2875-00537609
23 - Discipline Review Letter Quality 12/23/19	TEVA-MDL2875-00397165
24 - Curriculum Vitae Elisabeth Gray	N/A
25 - FDA Approval Letter 9/23/14 ANDA 091519/S-003	TEVA-MDL2875-00133642
26 - FDA Approval Letter 1/30/15 ANDA 090642/S-001	TEVA-MDL2875-00354034
Stefan Karlsson – 03.18.2021 - Transcript	N/A
27 - Curriculum Vitae Stefan Karlsson	TEVA-MDL2875-DEPS-000010-12
28 - E-mail Exchange 4/23/18 Subject, Genotoxic IMP in Amlodipine Valsartan	TEVA-MDL2875-00640915
29 - E-mail Thread 6/22/18 Subject, Urgent and Important, Genotoxic Impurity Notification	TEVA-MDL2875-00640935-37
30 - E-mail Thread 6/26/18 Subject, Urgent and Important, Genotoxic Impurity	TEVA-MDL2875-00640938-39
31 - E-mail Thread 6/26/18 Subject, API Comments Tri-Weekly	TEVA-MDL2875-00102417
32 - E-mail Thread 6/26/18 Subject, Urgent and Important, Genotoxic Impurity Notification	TEVA-MDL2875-00102419-22
33 - E-mail Thread 10/11/18 Subject, Teva Corporate Audit Huahai	TEVA-MDL2875-00102627
34 - E-mail Thread 6/26/18 Subject, GNTM-CORP-QRM 2018-018 Has Been Added	TEVA-MDL2875-00640941-46
35 - E-mail Thread 7/5/18 Subject, Valsartan RoS Mylan	TEVA-MDL2875-00508417
36 - E-mail Thread 7/5/18 Subject, Valsartan Alternative Source	TEVA-MDL2875-00508418
37 - E-mail Thread 7/5/18 Subject, Valsartan	TEVA-MDL2875-00508419-20
38 - E-mail Thread 7/5/18 Subject, Valsartan TAP India	TEVA-MDL2875-00102525-27
39 - E-mail Thread 7/6/18 Subject, Valsartan Synthesis	TEVA-MDL2875-00102494-96
40 - E-mail Thread 7/6/18 Subject, Valsartan RoS	TEVA-MDL2875-00380502-03

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REVIEW MATERIALS PROVIDED	BATES NOS.
41 - E-mail Thread 7/6/18 Subject, Valsartan RoS Mylan	TEVA-MDL2875-00508428-29
42 - Drug Master File Valsartan Ph.Eur	TEVA-MDL2875-00508430
43 - E-mail Thread 9/18/18 Subject, Jubilant NDEA Issue?	TEVA-MDL2875-00641058
44 - E-mail Thread 7/17/18 Subject, Lopress Tablets	TEVA-MDL2875-00102566-68
45 - E-mail Thread 7/19/18 Subject, Valsartan and Other Sartans	TEVA-MDL2875-00508500
46 - E-mail Thread 3/18/14 Subject, Genotoxic Impurities	TEVA-MDL2875-00101997-98
47 - A Rationale for Determining, Testing And Controlling (Muller)	TEVA-MDL2875-00101999
48 - E-mail Thread 9/20/16 Subject, Amlodipine Valsartan DCP Day 180 AR PSRPH	TEVA-MDL2875-00102319-20
49 - E-mail Thread 10/23/18 Subject, DMF Meeting R&D Preparation	TEVA-MDL2875-00102646
Narendra Vadsola – 03.24.2021 - Transcript	N/A
50 - Curriculum Vitae Narendra Vadsola	TEVA-MDL2875-DEPS-000014-17
51 - GxP Audit Program Corp-0126 2/7/18	TEVA-MDL2875-00489333
52 - E-mail Thread 9/5/11 Subject, Zheijang Huahai Audit on Valsartan	TEVA-MDL2875-00244213-14
53 - Audit Report on ZHP Chuannan Site 9/2/11	TEVA-MDL2875-00244215
54 - E-mail Thread 12/9/13 Subject, ZHP (Chuannan Site Audit Report)	TEVA-MDL2875-00244724
55 - Audit Report ZHP 12/24-28/12 GMP Audit	TEVA-MDL2875-00244725-81
56 - ZHP Linhai Audit Report August 2016	TEVA-MDL2875-00245934-73
57 - ZHP Xunqiao Linhai Audit Report June 2015	TEVA-MDL2875-00399765
58 - Audit Report 5/21-25-2018 GMP Audit ZHP00310356-62	ZHP00310356-62
59 - E-mail Thread 8/14/18 Subject, Item Was Updated by Honglin Ju	TEVA-MDL2875-00247597-99
60 - E-mail Thread 8/31/18 Subject, ZHP (Chuannan Site) Linhai	TEVA-MDL2875-00118146
61 - ZHP Audit Report May 2018	TEVA-MDL2875-00118147-08
62 - ZHP Audit Report Chuannan Site May 2018	TEVA-MDL2875-00118210
63 - Audit Report 9/25/18 Audit ID 177269	TEVA-MDL2875-00318608-27
64 - E-mail Thread 10/2/18 Subject, Draft Executive Summary Huahai Audit	TEVA-MDL2875-00522655-60
65 - E-mail Thread 10/16/18 Subject, Audit Report Zhejiang Huahai	TEVA-MDL2875-00073283
66 - E-mail Thread 10/23/18 Subject, Final Draft Audit Report	TEVA-MDL2875-00031904-06
67 - E-mail Thread 10/31/18 Subject, Audit 177269	TEVA-MDL2875-00400391-00
68 - E-mail Thread 9/20/16 Subject, Amlodipine Valsartan DCP	TEVA-MDL2875-00102319-20
69 - E-mail Thread 12/4/18 Subject, Final Copy Of ZHP Audit Report	TEVA-MDL2875-00319659-63
70 - E-mail Thread 3/26/19 Subject, Huahai Visit & Protocol Basis Assessment	TEVA-MDL2875-00484032-36
71 - E-mail Thread 9/24/12 Subject, Training at Goa Manufacturing	TEVA-MDL2875-00734327
72 - Mylan Laboratories Audit Report March 2015	TEVA-MDL2875-00247059-82
73 - Mylan Laboratories Audit Report March 2018	TEVA-MDL2875-00318831-54
74 - E-mail Thread 7/25/18 Subject, Item Was Created by Narendra Vadsola	TEVA-MDL2875-00247590-91
75 - E-mail Thread 9/19/18 Subject, Mylan Laboratories Limited	TEVA-MDL2875-00137459-72
76 - E-mail Thread 3/5/19 Subject, Mylan Laboratories Limited	TEVA-MDL2875-00738245-64

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REVIEW MATERIALS PROVIDED	BATES NOS.
77 - E-mail Thread 3/5/19 Subject, Audit Report Request	TEVA-MDL2875-00320637-38
78 - Mylan Executive Summary	TEVA-MDL2875-00320639-73
Raphael Nudelman – 04.08.2021 - Transcript	N/A
79 - Notice of Deposition	N/A
80 - Response to Plaintiffs' Document Requests	N/A
81 - Resumé Raphael Nudelman, Ph.D., ERT	TEVA-MDL2875-DEPS-000019-24
82 - LinkedIn Raphael Nudelman, Ph.D., ERT	TEVA-MDL2875-DEPS-000025-26
83 - No Exhibit	No Exhibit
84 - No Exhibit	No Exhibit
85 - Audit Report On ZHP (Chuannan Site) 9/2/11	TEVA-MDL2875-00051288
86 - No Exhibit	No Exhibit
87 - Auditing of API Manufacturers 3/27/12	TEVA-MDL2875-00102747
88 - E-mail, 7/4/12 Subject, Genotoxicity Evaluation for Valsartan (Azide Route)	TEVA-MDL2875-00539802
89 - Computational Toxicology Report for Valsartan Reagents and Intermediates 7/19/12	TEVA-MDL2875-00259857
90 - E-mail Thread 8/1/12 Subject, Acetaldehyde Toxicity	TEVA-MDL2875-00514864-66
91 - No Exhibit	No Exhibit
92 - No Exhibit	No Exhibit
93 - E-mail Thread 3/30/14 Subject, Amlodipine Besilate	TEVA-MDL2875-00158436-39
94 - Caspofungin 50-70 mg Powder for Concentrate For Solution for Infusion 3.2.P.2	TEVA-MDL2875-00917440-19
95 - Computational Mutagenicity Report For Potential Impurity In Valsartan 10/14/15	TEVA-MDL2875-00259986-87
96 - E-mail Thread 6/15/16 Subject, Toxicology of Hydrolyzed Calpronium Chloride	TEVA-MDL2875-00158463-69
97 - No Exhibit	No Exhibit
98 - E-mail Thread 12/19/17 Subject, Valsartan Proposal for API Specifications Revision US	TEVA-MDL2875-00082321-24
99 - Computational Mutagenicity and Control Recommendations For Potential Impurities In Valsartan	TEVA-MDL2875-00158698-05
100 - Quality Risk Management for Cross Contamination Control	TEVA-MDL2875-00260122
101 - E-mail Thread 6/28/18 Urgent and Important Genotoxic Impurity Notification	TEVA-MDL2875-00056559-61
102 - Request for Safety Assessment of NDMA for Valsartan Dose 1x Daily for 320mg, 160mg, 80mg (June 28, 2018)	TEVA-MDL2875-00425812-14
103 - Toxicological Assessment for NDMA In Valsartan Drug Substance 6/29/18	TEVA-MDL2875-00158529
104 - No Exhibit	No Exhibit
105 - E-mail Thread 7/3/18 Subject, Urgent Valsartan Safety Assessment Request	TEVA-MDL2875-00158519-22

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REVIEW MATERIALS PROVIDED	BATES NOS.
106 - E-mail Thread 7/4/18 Subject Valsartan Urgent	TEVA-MDL2875-00056924-29
107 - E-mail Thread 7/4/18 Subject, Valsartan Urgent	TEVA-MDL2875-00514896-02
108 - E-mail Thread 7/4/18 Subject, Valsartan Urgent	TEVA-MDL2875-00020609-18
109 - E-mail Thread 7/5/18 Subject, Valsartan Urgent	TEVA-MDL2875-00158540-41
110 - E-mail Thread 7/5/18 Subject, Valsartan Urgent	TEVA-MDL2875-00495085
111 - E-mail Thread 7/5/18 Subject, Valsartan HHA draft V3 for Review	TEVA-MDL2875-00057083-85
112 - No Exhibit	No Exhibit
113 - No Exhibit	No Exhibit
114 - Draft HHA Valsartan Tablets 40, 80, 160, 320 Multiple Lots	TEVA-MDL2875-00057086-94
115 - No Exhibit	No Exhibit
116 - E-mail Thread 7/12/18 Subject, Valsartan	TEVA-MDL2875-00158544
117 - E-mail Thread 7/13/18 Subject, Valsartan Request from Hong Kong	TEVA-MDL2875-00540426-30
118 - E-mail Thread 7/13/18 Subject, EDQM Valsartan Provisional Limit Potential Impact on HHAs	TEVA-MDL2875-00021077-78
119 - Certification of Substances Department 8/10/18 Request for Information Relating to EU Referral Article 31 of Directive 2001/83/EC	N/A
120 - No Exhibit	No Exhibit
121 - E-mail Thread 9/6/18 Subject, Draft Valsartan Letter	TEVA-MDL2875-00552854-59
121A - NDMA Acceptable Limit (Handwritten Document From Plaintiff's Counsel Watt)	N/A
122 - E-mail Thread 10/22/18 Subject, NDMA & NDEA Limits	TEVA-MDL2875-00514942-43
123 - No Exhibit	No Exhibit
124 - E-mail Thread 12/27/18 Subject, Update 26th December 2018 RV Update	TEVA-MDL2875-00540783-88
125 - No Exhibit	No Exhibit
126 - E-mail Thread 3/26/19 Subject, Snodin & Elder Commentary	TEVA-MDL2875-00492386
127 - E-mail Thread 6/27/19 Subject, Request to be An Honorable Keynote Speaker	TEVA-MDL2875-00540844-46
128 - E-mail Thread 8/11/19 Subject, Editor's Spotlight Switzerland	TEVA-MDL2875-00158591-93
129 - Questionnaire for Excipient Nitrosamines Risk Evaluation	TEVA-MDL2875-00158603-09
130 - E-mail Thread 10/23/19 Subject, Ranitidine NDMA Formation	TEVA-MDL2875-00562588-97
131 - No Exhibit	No Exhibit
132 - No Exhibit	No Exhibit
133 - HHA Valsartan Tablets 40, 60,160, 320mg Multiple Lots	TEVA-MDL2875-00274341-49
134 - Toxicological Assessment for NDMA And NDEA in Parallel in Sartan-Drug Substances	TEVA-MDL2875-00773542
Daniel Barreto – 04.14.2021 & 04.15.2021 - Transcript	N/A
133 - Amended Notice to Take Videotaped Oral Deposition	N/A
134 - **C**onsulting Agreement	TEVA-MDL2875-DEPS-000027-031
135 - 9/16/16 E-mail, Thomas to Harle	TEVA-MDL2875-00116005-6007
136 - Teva Corporate Standards CORP-0175	TEVA-MDL2875-00042539
137 - Teva Corporate Standard, Corp-0896	TEVA-MDL2875-00586753
138 - 7/6/18 E-mail, Drape to Vanderweeen	TEVA-MDL2875-00495102-5104

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REVIEW MATERIALS PROVIDED	BATES NOS.
139 - Teva CORP-0092	TEVA-MDL2875-00020376
140 - 7/5/18 E-mail, Sawyer to Barak	TEVA-MDL2875-0934333-4435
141 - 7/4/18 E-mail, Barreto to Drape	TEVA-MDL2875-00020519-0525
142 - 7/12/18 E-mail, Barreto to Truemper	TEVA-MDL2875-00064409-4412
143 - 7/5/18 E-mail, Barreto to Koller-Dette	TEVA-MDL2875-00020744
144 - 7/6/18 E-mail, Sawyer to Drape	TEVA-MDL2875-00057196-7197
145 - 7/13/15 E-mail, Var to Koller-Dette	TEVA-MDL2875-00021073-1074
146 - 7/11/18 E-mail, Barreto to Lyons	TEVA-MDL2875-00020898-0903
147 - 7/8/18 E-mail, Barreto to Drape	TEVA-MDL2875-00020853-0854
148 - 7/9/18 E-mail, Osmian to Baeder	TEVA-MDL2875-00549865-9886
149 - 8/14/18 Valsartan Testing Strategy	TEVA-MDL2875-00042637-2649
150 - 12/13/18 E-mail, Drape to Barreto	TEVA-MDL2875-00067084-7087
151 - NDA/ANDA Field Alert	TEVA-MDL2875-00731926
152 - 11/16/18 E-mail, Redmond to Barreto	TEVA-MDL2875-00073603-3612
153 - Site Risk Assessment Protocol	TEVA-MDL2875-00415117
154 - 10/2/17 E-mail, McClain to Barreto	TEVA-MDL2875-00132980
155 - 2/15/19 E-mail, Lyons to Gray	TEVA-MDL2875-00546489-6492
156 - 6/15/16 E-mail, Myers to Cheasty	TEVA-MDL2875-00083812-3877
157 - 3/27/19 E-mail, Vanderweeen to Barreto	TEVA-MDL2875-00495893-5896
158 - 2/1/17 E-mail, Reitman to Hatt	TEVA-MDL2875-00246006
159 - 2/1/17 E-mail, Reitman to Hatt	TEVA-MDL2875-00246006
160 - 6/13/19 E-mail, Hoover to Hatt	TEVA-MDL2875-00400799-0905
161 - 1/1/19 E-mail, Weissbazak to Denac	TEVA-MDL2875-00067532-7537
162 - Risk Assessment for the Use of Valsartan	TEVA-MDL2875-00950663-0706
163 - Test Specification and Certificate of Analysis	TEVA-MDL2875-00000875
164 - Test Specification and Certificate of Analysis	TEVA-MDL2875-00020116
165 - Test Specification and Certificate of Analysis	TEVA-MDL2875-00015517
166 - GAP Analysis, Addition of Dupnista as an Alternative Manufacturing Site for Valsartan Tablets	TEVA-MDL2875-00242568-2678
167 - 3/24/16 Quality Agreement	TEVA-MDL2875-00020279
168 - Technical Agreement Between Actavis Group and Zhejiang Huahai	TEVA-MDL2875-00020213
169 - Amendment to Quality Agreement	TEVA-MDL2875-00020214
170 - Quality Agreement for Active Pharmaceutical Ingredient	TEVA-MDL2875-00020212
171 - 10/23/18 E-mail, Schwartz to Barreto	TEVA-MDL2875-00022589-2592
172 - 11/13/19 E-mail, Barreto to Drape	TEVA-MDL2875-00024488-4492
173 - 3/27/19 E-mail, Vanderweeen to Barreto	TEVA-MDL2875-00024041-4045
174 - 3/27/19 E-mail, Vanderweeen to Barreto	TEVA-MDL2875-00495893-5896
175 - 8/20/18 Letter, Truemper to Herber	TEVA-MDL2875-00065014-5016
176 - 8/8/19 Letter, Singh to Priester	N/A
177 - 1/4/19 E-mail, Dellarese to Truemper	TEVA-MDL2875-00014826-4827
178 - 1/1/19 E-mail, Ora Pharm1 Recalls to Truemper	TEVA-MDL2875-00014763
179 - 11/27/19 E-mail, Singh to Nase	TEVA-MDL2875-00717000-7014
180 - 9/29/19 E-mail, Etzioni to Fluch	TEVA-MDL2875-00071287-1303

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REVIEW MATERIALS PROVIDED	BATES NOS.
181 - 10/30/18 E-mail, Sawyer to Barreto	TEVA-MDL2875-00060028-0034
182 - 10/30/18 E-mail, Sawyer to Barreto	TEVA-MDL2875-00060028-0034
183 - Test Result Report	TEVA-MDL2875-00917708-7715
Claire Lyons – 04.27.2021 - Transcript	N/A
184 - Claire Lyons' Curriculum Vitae	TEVA-MDL2875-DEPS-000036-37
185 - E-mail chain, with attachments	TEVA-MDL2875-00042531-42649
186 - E-mail chain with attachments	TEVA-MDL2875-00040869-40870
187 - E-mail chain with attachments	TEVA-MDL2875-00951893-1897
188 - E-mail chain	TEVA-MDL2875-00084100-84101
189 - E-mail chain	TEVA-MDL2875-00649535-9545
190 - E-mail chain	TEVA-MDL2875-00103248-3249
191 - E-mail chain	TEVA-MDL2875-00041380-41381
192 - E-mail chain	TEVA-MDL2875-00042885-42887
193 - E-mail chain	TEVA-MDL2875-00043320-43326
194 - E-mail chain	TEVA-MDL2875-00650876-880
195 - E-mail chain	TEVA-MDL2875-00084367-84369
196 - E-mail chain	TEVA-MDL2875-00409210-9212
197 - 10/24/18 E-mail	TEVA-MDL2875-00044292-44294
198 - E-mail chain	TEVA-MDL2875-00409313-9318
199 - E-mail chain with attachments	TEVA-MDL2875-00952047-952050
200 - E-mail chain	TEVA-MDL2875-00122205-122208
201 - E-mail chain with attachments	TEVA-MDL2875-00050845-50860
202 - E-mail chain, with attachment	TEVA-MDL2875-00048605-48610
203 - E-mail chain	TEVA-MDL2875-00414544-546
204 - Warning Letter, Zhejiang Huahai Pharmaceutical	N/A
205 - PowerPoint, FDA Enforcement of CGMPs	TEVA-MDL2875-00904538
206 - August 15, 2018 FDA Recall Notice	N/A
207 - NDA/ANDA Field Alert	TEVA-MDL2875-00077328
208 - E-mail chain	TEVA-MDL2875-00551587-1588
209 - July 12, 2018 letter	TEVA-MDL2875-00118084
210 - E-mail chain with attachment	TEVA-MDL2875-00324024-4027
211 - Response to queries on Valsartan received from customer Teva	TEVA-MDL2875-00324027
212 - July 6, 2018 memo	TEVA-MDL2875-00649442
Anthony Binsol – 05.13.2021 - Transcript	N/A
153 - Site Risk Assessment Protocol	TEVA-MDL2875-00415117
232 - Finished Product Material Name/Description Finished Product Lot Numbers, Bulk Lot API Supplier	TEVA-MDL2875-00429901
245 - Notice of Deposition	N/A
246 - Curriculum Vitae Anthony R. Binsol	TEVA-MDL2875-DEPS-000043-46
247 - 7/2/19 Investigation Report For gDR# 1336473	TEVA-MDL2875-00049024

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REVIEW MATERIALS PROVIDED	BATES NOS.
248 - Response to Queries on Valsartan Received from Customer Teva	TEVA-MDL2875-00684220
249 - Google Patents Preparation Method Of Valsartan	(No Bates)
250 - EPA Technical Fact Sheet NDMA 1/2014	TEVA-MDL2875-00280442
251 - European Journal of Pharmaceutical Sciences Overall Impact of the Regulatory Requirements For Genotoxic Impurities On the Drug Development Process	TEVA-MDL2875-00259905
252 - Strategies for the Identification, Control And Determination of Genotoxic Impurities in Drug Substances	TEVA-MDL2875-00259910
253 - Commercial Invoice Packing List Certificate of Analysis	TEVA-MDL2875-00166889
254 - Table of Contents Residual Solvents Evaluation for Drug Product Amlodipine	TEVA-MDL2875-00006479
255 - USP 30 Residual Solvents Chemical Tests	N/A
256 - E-mail Thread 1/31/19 Subject, Copy of FDA-copy Valsartan and Valsartan HCTZ Finished Product List	TEVA-MDL2875-00060894-95
257 - E-mail Thread 2/22/12 Subject, Retest of Batch F33155	TEVA-MDL2875-00617605-08
258 - E-mail Thread 11/14/14 Subject, Updating the Batch Manufacturing Documentation at Arrow Malta	TEVA-MDL2875-00498987-90
259 - 3/24/17 Certificate of Conformance QAG-09	TEVA-MDL2875-00161707 TEVA-MDL2875-00161713
260 - E-mail Thread 6/10/16 Subject, Toxicology Of Hydrolyzed Calpronium Chloride	TEVA-MDL2875-00514869-73
261 - E-mail Thread 1/31/11 Subject, DK/1844/1-2/DC	TEVA-MDL2875-00444018-20
262 - 3/24/17 Certificate of Conformance	TEVA-MDL2875-00161707 TEVA-MDL2875-00161713
263 - E-mail Thread 5/3/18 Subject, Genotoxic Imp In Amlodipine/ Valsartan FP	TEVA-MDL2875-00508410-15
264 - E-mail Thread 9/26/17 Subject, Valsartan Huahai RS Method	TEVA-MDL2875-00521020-25
265 - E-mail Thread 6/28/17 Subject, Results of Aml Imp D- Phase II	TEVA-MDL2875-00521015-17
266 - E-mail Thread 7/19/18 Subject, Valsartan TAPI India Urgent Conformation Needed	TEVA-MDL2875-00021238-46
Pan Lin – 05.26.2021 & 05.27.2021 - Transcript	N/A
267 - Pan Lin's Resume and LinkedIn profile	TEVA-MDL2875-DEPS-000051-52
268 - Document titled GxP Audit Program, Corporate Standards CORP-0126	TEVA_MDL2875-00489580
269 - E-mail chain with attachment	TEVA_MDL2875_00155644 - 55645
270 - E-mail chain with attachment	TEVA_MDL2875_00244213 - 244215
271 - 12/9/13 e-mail with attachment	TEVA_MDL2875_00244724 - 4787
272 - E-mail chain	TEVA-MDL2875-00736525 - 6551
273 - ZHP (Chuannan site) - Linhai Zhejiang China Audit Report, June 2015	TEVA_MDL2875_00399168-99246

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REVIEW MATERIALS PROVIDED	BATES NOS.
274 - E-mail chain dated 6/28/18	TEVA-MDL2875-00791611 - 617
275 - FDA Form 483 for an inspection the Agency conducted of Chuannan in May 2017	N/A
276 - Letter dated 9/15/17 from FDA to Zhejiang Huahai Pharmaceutical with attachment	N/A
277 - E-mail chain dated 7/14/2018	TEVA-MDL2875-00169060 - 062
278 - E-mail chain dated 8/8/2018	TEVA-MDL2875-00736525 - 551
279 - E-mail chain dated 9/21/2018	TEVA-MDL2875-00324990 - 992
280 - E-mail chain dated 9/23/2018	TEVA-MDL2875-00325033 - 035
281 - E-mail chain dated 9/27/2018	TEVA-MDL2875-00022372 - 373
282 - E-mail chain dated 9/30/2018 with attachment	TEVA-MDL2875-00318605- 627
283 - E-mail chain dated 9/27/2018	TEVA-MDL2875-00485626 - 627
284 - E-mail chain dated 9/18/19	ZHP02499075 - 081
285 - E-mail chain dated 9/27/2018 with attachment	TEVA-MDL2875-00318577- 583
FDA GUIDANCES AND DOCUMENTS	
2008.12.00 – Guidance for Industry – Genotoxic and Carcinogenic impurities in drug substances and products: Recommended approaches	N/A
2008.12.16 – Federal Register Vol 73 – No 242 Summary – FDA announcing the availability of a draft guidance for industry entitled "genotoxic and Carcinogenic Impurities in Drug Substances…."	N/A
2012.06.00 - Guidance for Industry S2(R1) Genotoxicity Testing and data interpretation for pharmaceuticals intended for human use.	N/A
2015.06.09 - M7(R1) addendum to ICH M7: assessment and control of DNA reactive impurities in pharmaceuticals to limit potential carcinogenic risk.	N/A
2017.03.31 - ICH Harmonised Guideline - assessment and control of DNA impurities in pharmaceuticals to limit potential carcinogenic risk	N/A
2018.03.00 – M7(R1) assessment and control of DNA reactive impurities in pharmaceuticals to limit potential carcinogenic risk – guidance for industry	N/A
2018.12.11 Combined Direct Injection N-Nitrosodimethylamine (NDMA) and NNitrosodiethylamine (NDEA) Impurity Assay	N/A
2019.01.28 – Combined N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay	N/A
2019.04.19 Combined Direct Injection N-Nitrosodimethylamine (NDMA), N-Nitrosodiethylamine (NDEA), N-Nitrosoethylisopropylamine (NEIPA), N-Nitrosodiisopropylamine (NDIPA), and N-Nitrosodibutylamine (NDBA) Impurity Assay by GC-MS/MS	N/A
2019.04.29 Combined Headspace N-Nitrosodimethylamine (NDMA), N-Nitrosodiethylamine (NDEA), N-Nitrosoethylisopropylamine (NEIPA), and N-Nitrosodiisopropylamine (NDIPA) Impurity Assay by GC-MS/MS	N/A

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REVIEW MATERIALS PROVIDED	BATES NOS.
2019.05.21 Liquid Chromatography-High Resolution Mass Spectrometry (LC-HRMS) Method for the Determination of Six Nitrosamine Impurities in ARB Drugs	N/A
2019.07.24 Development and validation of a RapidFire-MS/MS method for screening of nitrosamine carcinogen impurities N-Nitrosodimethylamine (NDMA), N-Nitrosodiethylamine (NDEA), N-Nitrosoethylisopropylamine (NEIPA), N-Nitrosodiisopropylamine (NDIPA), NNitrosodibutylamine (NDBA) and N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) in ARB drugs	N/A
2020.06.29 - M7 Assessment and Control of DNA reactive impurities pharmaceuticals to limit potential carcinogenic risk – question and answers	N/A
2020.10.02 – FDA Webinar – Overview of the guidance for industry: control of nitrosamine impurities in human drugs	N/A
2021.02.00 – Control of nitrosamine impurities in human drugs – guidance for industry	N/A
2021.03.29 – Nitrosamines as impurities in drugs; health risk assessment and mitigation workshop day 1	N/A
SCIENTIFIC LITERATURE	
1979.06.04 - Molecular and cellular aspects of carcinogen screening tests	N/A
1991 - Peto - Cancer Research-Effects on 4080 Rats of Chronic Ingestion 6415	N/A
1991 - Peto - Dose and Time Relationships for Tumor Induction 6452	N/A
2002.00.00 - Concise International Chemical Assessment Doc 38 – N-nitrosodimethylamine	N/A
2006.01.18 - A rationale for determining, testing and controlling specific impurities in pharmaceuticals that possess potential for genotoxicity. *Regulatory Toxicology and Pharmacology*, (Muller, et al.)	N/A
2007 - A. Fristachi - (Journal of Water and Health) Estimation of the Total Daily Oral Intake of NDMA Attributable to Drinking Water	N/A
2009.06.08 - N-nitrosodimethylamine: much more than a solvent	N/A
2010.00.00 - Strategies for the identification, control and determination of genotoxic impurities in drug substances: a pharmaceutical industry perspective	N/A
2013.01.22 - Analysis of N-nitrosodimethylamine (NDMA) in water using GC triple quadruple mass spectrometry	N/A
2016 – Genotoxic Impurities Evaluation in API	N/A
2010 - Genotoxic Impurities: From Structural Alerts to Qualification, *Organic Process Research & Devel.* (Sondin)	TEVA-MDL2875-00259836
2009 - Approaches to Assessment, Testing Decisions, and Analytical Determination of Genotoxic Impurities in Drug Substances, *Organic Process Research & Devel.* (Pierson, et al.) 2009	TEVA-MDL2875-00539900

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2011 - Review: Overall impact of the regulatory requirements for genotoxic impurities on the drug development process. European J. of Pharmaceutical Sciences, (Giordani, et al.)	TEVA-MDL2875-00259905
2011 - Review: Strategies for the identification, control and determination of genotoxic impurities in drug substances: A pharmaceutical industry perspective, *J. of Pharmaceutical and Biomedical Analysis* (Raman, et al.)	TEVA-MDL2875-00259910
2019 - Review: Lesson Learnt from Recall of Valsartan and Other Angiotensin II Receptor Blocker Drugs Containing NDMA and NDEA Impurities AAPS PharmSciTech, (Charoo, et al.)	TEVA-MDL2875-00426245
2010 - A Detailed Study of Suofonate Ester Formation and Solvolysis Reaction Rates and Application toward Establishing Sulfonate Ester Control in Pharma Manufacturing, *Organic Process Research & Devel.* (Teasdale, et al.)	TEVA-MDL2875-00539898
2010 - Control of Genotoxic Impurities in Active Pharmaceutical Ingredients: A Review and Perspective, Organic Process Research & Development, (Robinson)	TEVA-MDL2875-00259900
2010 - Review: Recent advances in trace analysis of pharmaceutical genotoxic impurities, *J. of Pharmaceutical and Biomedical Analysis* (Liu, et al.)	TEVA-MDL2875-00539908
DEFENDANT DOCUMENTS PRODUCED	
NDMA/NDEA test results	TEVA-MDL2875-00063060 TEVA-MDL2875-00539061-00539066 TEVA-MDL2875-00539082-00539087 TEVA-MDL2875-00693421, 00693422, 00693423, 00693424 TEVA-MDL2875-00765603 TEVA-MDL2875-00765609
Valsartan communication to customers_Nov2018.pdf (Mylan root cause)	TEVA-MDL2875-00019995
Quality Agreement with ZHP	TEVA-MDL2875-00020212 TEVA-MDL2875-00020279
2018.07.04 Draft Health Hazard Assessment	TEVA-MDL2875-00020676
Evaluation report regarding NDMA.pdf (ZHP root cause)	TEVA-MDL2875-00041861
2019.07.02 Investigation Report for gDR# 1336473	TEVA-MDL2875-00048658
0000.00.00 Letter from ZHP	TEVA-MDL2875-00056569
2018.07.04 Draft Health Hazard Assessment	TEVA-MDL2875-00057056
2018.09.14 Rapporteru's JOINT preliminary assessment report on Amlodipine-Valsartan Mylan EMEA/H/A-31	TEVA-MDL2875-00059354
2018.07.06 Quality Assessment for Recall Evaluation of Valsartan Single and Combination Products	TEVA-MDL2875-00120362
2020.04.21 Global Nitrosamine Project – Primary Amine Position Paper	TEVA-MDL2875-00130591 TEVA-MDL2875-00158852

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REVIEW MATERIALS PROVIDED	BATES NOS.
April 2020 – Global Nitrosamine Project – Primary Amine Position Paper – Greg Ott	TEVA- MDL2875- 00130592
2021.10.18 Change Notification	TEVA-MDL2875-00147386
2014.03.30 Toxicological Qualification of Impurity in Amlodipine/Valsartan Tablets	TEVA-MDL2875-00158435
2014.03.30 Toxicological Qualification of Impurity in Amlodipine/Valsartan Tablets	TEVA-MDL2875-00158440
2018.08.23 Email from K. Praveen to M. Ohana re Derek, Sarah Evaluation	TEVA-MDL2875-00158561
2020.02.06 Computational Mutagenicity and Control Recommendations for Potential Impurities in Valsartan	TEVA-MDL2875-00158698
Negligible Risk of Primary Amines to Form Stable Secondary N-Nitrosamines in Active Pharmaceutical Ingredients	TEVA-MDL2875-00158853
2012.01.17 Change Request	TEVA-MDL2875-00159856
2019.07.29 Email from A. Hafif to D. Wang re Emailing: TPI01065	TEVA-MDL2875-00168411
2019.07.30 Email from A. Hafif to D. Wang re Emailing: gDR # 1336473	TEVA-MDL2875-00168436
2019.06.20 gDR - Full Report	TEVA-MDL2875-00168437
2020.03.10 Guidance on the Risk Evaluation Process for the Potential Formation of Nitrosamine Impurities	TEVA-MDL2875-00171820
2012.07.19 Computational Toxicology Report for Valsartan Reagents and Intermediates	TEVA-MDL2875-00259857
2015.10.14 Computational Mutagenicity Report for Potential Impurity in Valsartan	TEVA-MDL2875-00259986
2015.10.14 Computational Mutagenicity Report for Potential Impurity in Valsartan	TEVA-MDL2875-00259993
2016.03.09 Email from D. Doron to S. Biloglav re Amlodipine Besilate	TEVA-MDL2875-00260009
2016.03.09 Toxicological Qualification of EP Impurity D in Valsartan and Hydrochlorothiazide Tablets	TEVA-MDL2875-00260014
2017.08.16 Analytical Method for Drug Product	TEVA-MDL2875-00260052
2018.07.03 Draft Health Hazard Assessment	TEVA-MDL2875-00260089
2018.12.17 Computational Mutagenicity and Control Recommendations for Potential Impurities in Valsartan	TEVA-MDL2875-00260232
2020.03.24 Expert Report of Professor Dr. Jan Tytgat	TEVA-MDL2875-00260391
2020.04.21 Computational Mutagenicity and Control Recommendations for Potential Impurities in Valsartan	TEVA-MDL2875-00260411
2018.07.06 – Global Quality Report: 2018-CQ-020-1v1 – Quality Assessment for Recall Evaluation of Valsartan Single and Combination Products	TEVA-MDL2875-00274360
2018.09.10 Rapporteur's JOINT Preliminary Assessment Report	TEVA-MDL2875-00324743
2018.09.10 Rapporteur's JOINT Preliminary Assessment Report	TEVA-MDL2875-00324793
2018.10.31 Submission to EMA Article 31 Referral	TEVA-MDL2875-00328431
2018.10.30 TAPI Determination of N-Nitrosodimethylamine Content in Valsartan By GCHS Method Validation Report	TEVA-MDL2875-00328918
Background – Nitrosamine Group of Carcinogens	TEVA-MDL2875-00329942

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REVIEW MATERIALS PROVIDED	BATES NOS.
2020.02.06 Computational Mutagenicity and Control Recommendations for Potential Impurities in Valsartan	TEVA-MDL2875-00351418
2018.11.16 Interim Quality Assessment Report	TEVA-MDL2875-00411263
2018.11.26 Mylan NDEA Investigation Report	TEVA-MDL2875-00415333
2018.06.28 Request for Safety Assessment of N-nitrosodimethylamine (NDMA) for Valsartan dose 1x daily for 320mg, 160mg and 80mg	TEVA-MDL2875-00425812
2018.11.19 HEALTH HAZARD ASSESSMENT, VALSARTAN CONTAINING PRODUCTS	TEVA-MDL2875-00426004
2019.02.15 Letter from Department of Health and Human Services FDA to Teva Pharmaceutical Industries LTD (Kerri McCullough Wood)	TEVA-MDL2875-00437866
2018.11.30 API Testing Results	TEVA-MDL2875-00539494
2018.11.14 – email from D. Barreto to Carlos Baerga, et al. re: US samples for testing	TEVA-MDL2875-00558068
ZHP Assessment	TEVA-MDL2875-00559763
Mylan Assessment	TEVA-MDL2875-00559764
Mylan API Testing Results	TEVA-MDL2875-00560868
5.21.19 "Liquid Chromatography-High Resolution Mass Spectrometry (LC-HRMS) Method for the Determination of Six Nitrosamine Impurities in ARB Drugs."	TEVA-MDL2875-00563021
June 21, 2018 ZHP Notice and updated Notice to Teva of NDMA in Valsartan API	TEVA-MDL2875-00640941 TEVA-MDL2875-00640947
Quality Technical agreement for active pharmaceutical ingredients	TEVA-MDL2875-00679902
2018.11.16 MAC Follow Up Meeting	TEVA-MDL2875-00768747
2019.03.13 Toxicological Assessment for N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) in Parallel in Sartan-Drug Substances	TEVA-MDL2875-00773542
2013.05.12 Change Control Instance Report	TEVA-MDL2875-00950662
2013.08.06 Risk Assessment for the use of Valsartan sourced from a new dedicated workshop with changes in CEP at Actavis Ltd	TEVA-MDL2875-00950663
ANDA077530	TEVA-MDL2875-ANDA077530
ANDA090642	TEVA-MDL2875-ANDA090642
ANDA091235	TEVA-MDL2875-ANDA091235
ANDA091519	TEVA-MDL2875-ANDA091519
ANDA200435	TEVA-MDL2875-ANDA200435
2014.09.15 Email from S. Mukherjee to Mylan	MYLAN-MDL2875-002757214
Triethylamine Safety Data Sheet	MYLAN-MDL2875-00257215
2014.10.16 Email from L. Zheng to S. Suri re: Valsartan API	ZHP01748896
2019.03.01 Email from J. Cheng to K. Xiaxia re: Vertex Valsartan	ZHP02118072
2016.12.22 Email from F. Dsouza to Z. Xu re: valsartan from Huahai --- Impurities & Unknown peaks	ZHP02118712
2019.02.28 Email from L.Q. Ming to K. Xiaxia re: vertex	ZHP02630924
TEVA SOPs	
SOP01445 V7.0.pdf	TEVA-MDL2875-00015267

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REVIEW MATERIALS PROVIDED	BATES NOS.
SOP01193 ver.5.pdf	TEVA-MDL2875-00015268
SOP00197.Handling Complaints.pdf	TEVA-MDL2875-00015274
SOP00043 V16.0.pdf	TEVA-MDL2875-00015276
SOP00099. Manufacturing Deviation Report.pdf	TEVA-MDL2875-00015280
MALTA2013\SOP list.pdf	TEVA-MDL2875-00015949
MALTA2015\SOP list.pdf	TEVA-MDL2875-00016021
Translation of SOP00238 Ver.12.0 Raw Materials Samples Testing, Handling and Storage.pdf	TEVA-MDL2875-00019776
Translation of SOP00296 Ver.8.0 Raw Material and Packaging Material Testing Policy.pdf	TEVA-MDL2875-00019785
Assay, Content Uniformity Determination and Identification by ChromatographicMethods for Laboratories.pdf	TEVA-MDL2875-00019798
Determination of ImpuritiesDegradation Products by HPLC and GC Methods.pdf	TEVA-MDL2875-00019811
QDS0002948 RM Method.pdf	TEVA-MDL2875-00019824
QDS0005000 RM GC Method.pdf	TEVA-MDL2875-00019838
3.2.P.5.1Release-Stability Specifications - US. QDP0033694.pdf	TEVA-MDL2875-00019852
3.2.P.5.2 Assay & IDD_2.pdf	TEVA-MDL2875-00019863
3.2.P.5.2 Dissolution Test by HPLC (SI)_2.pdf	TEVA-MDL2875-00019899
3.2.P.5.2 Identification Test (SI)_2.pdf	TEVA-MDL2875-00019911
3.2.P.5.2 UOC Test by HPLC (SI)_2.pdf	TEVA-MDL2875-00019919
Rationale for Abbreviation of Monographs of Raw Materials.pdf	TEVA-MDL2875-00019930
2019.11.13 – ID: DP-QA-01-014 - Standard Operating Procedure Policy for Assessment and Control of Mutagenic Impurities in Drug Substances	TEVA-MDL2875-00351416
2018.10.04 DETERMINATION OF RESIDUAL NDMA,NDEA,NIEA AND NDIA CONTENT IN VALSARTAN API	TEVA-MDL2875-00392510
2018.10.18 DETERMINATION OF RESIDUAL NDMA,NDEA,NIEA AND NDIA CONTENT IN VALSARTAN API	TEVA-MDL2875-00392511
CORP-0126 – "Audit Program"	TEVA-MDL2875-00508076 TEVA-MDL2875-00778630 TEVA-MDL2875-00155666
CORP-0005 – "Material Purchasing, Reiving, Storage and Distribution"	TEVA-MDL2875-00155086 TEVA-MDL2875-00509073 TEVA-MDL2875-00499372
CORP-00533 – "Batch Disposition"	TEVA-MDL2875-00398311
CORP-0008 "Quality Control Laboratory Charter"	TEVA-MDL2875-00398335 TEVA-MDL2875-00779102 TEVA-MDL2875-00350103

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REVIEW MATERIALS PROVIDED	BATES NOS.
	TEVA-MDL2875-00774070 TEVA-MDL2875-00567106
CORP-0051 "Equivalency of APIs"	TEVA-MDL2875-00629637
CORP-0150 – "Process Validation"	TEVA-MDL2875-00100202
CORP-0433 – "ICP-MS Elemental Impurities Method Validation"	TEVA-MDL2875-00066348
Corp-0046 (Outsourced Activities) "Contract Manufacture and Analysis"	TEVA-MDL2875-00440402
CORP-0114 "Investigations"	TEVA-MDL2875-00317347 TEVA-MDL2875-00096477 TEVA-MDL2875-00567107 TEVA-MDL2875-00156038
CORP-0111 "3rd Party Suppliers and Contract Laboratories Compliance Status"	TEVA-MDL2875-00631359
CORP-0912 "In-Vitro Bioequivalence, Analytical Validation and Testing Requirements Supported by Bioanalytical Method Validation."	TEVA-MDL2875-00133901
CORP-0141 "Q9 Quality Risk Management"	TEVA-MDL2875-00155193
CORP-0070 "Risk Assessment; Computerized Systems"	TEVA-MDL2875-00155385
CORP-1043 "Determination of Related Substances by Chromatographic Methods"	TEVA-MDL2875-00172134 TEVA-MDL2875-00470559 TEVA-MDL2875-00774057
CORP-1045 "Chromatographic Procedure for Assay and Identification Determination Tests"	TEVA-MDL2875-00401152 TEVA-MDL2875-00470560 TEVA-MDL2875-00307668
Corp-1041 "Testing Practices and Procedures"	TEVA-MDL2875-00470558 TEVA-MDL2875-00168152

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REVIEW MATERIALS PROVIDED	BATES NOS.
CORP-0348 "Annual Review for Commercial Drug Product"	TEVA-MDL2875-00482659 TEVA-MDL2875-00778636 TEVA-MDL2875-00160168 TEVA-MDL2875-00586594
CORP-0539 "Management of Quality Technical Agreements"	TEVA-MDL2875-00331419
CORP-0097 "Change Control"	TEVA-MDL2875-00498352 TEVA-MDL2875-00778639 TEVA-MDL2875-00152579 TEVA-MDL2875-00276137
CORP-0134 "Auditing of API Manufacturers"	TEVA-MDL2875-00102747 TEVA-MDL2875-00155338
CORP-0780 SOP for Health Hazard and Safety Assessments	TEVA-MDL2875-00696907 TEVA-MDL2875-00505717 TEVA-MDL2875-00780427 TEVA-MDL2875-00351096 TEVA-MDL2875-00024387 TEVA-MDL2875-00066198
CORP-1043 "Determination of Related Substances by Chromatographic Methods"	TEVA-MDL2875-00305802
CORP-1327 "Guidance on the Risk Evaluation Process for the Potential Formation of Nitrosamine Impurities"	TEVA-MDL2875-00657009
EXEMPLAR BATCH RECORDS	
Test Specification and Certificate of Analysis	TEVA-MDL2875-00016498
Certificate of Analysis	TEVA-MDL2875-00019752
Certificate of Analysis	TEVA-MDL2875-00019756
Certificate of Analysis	TEVA-MDL2875-00019760

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REVIEW MATERIALS PROVIDED	BATES NOS.
Certificate of Analysis	TEVA-MDL2875-00019764
Certificate of Analysis	TEVA-MDL2875-00019768
Certificate of Analysis	TEVA-MDL2875-00019772
2017.11.04 - Certificate of Conformance	TEVA-MDL2875-00149885
2017.12.04 - Certificate of Conformance	TEVA-MDL2875-00149886
2017.04.11 - Certificate of Conformance	TEVA-MDL2875-00149887
2017.06.06 - Certificate of Conformance	TEVA-MDL2875-00149888
2017.06.19 - Certificate of Conformance	TEVA-MDL2875-00149889
2017.06.06 - Certificate of Conformance	TEVA-MDL2875-00149890
2017.06.13 - Certificate of Conformance	TEVA-MDL2875-00149891
2017.06.12 - Certificate of Conformance	TEVA-MDL2875-00149892
2016.08.22 - Certificate of Conformance	TEVA-MDL2875-00149893
2017.07.17 - Certificate of Conformance	TEVA-MDL2875-00154314
2017.07.31 - Certificate of Conformance	TEVA-MDL2875-00154315
2017.10.05 - Certificate of Conformance	TEVA-MDL2875-00154316
2017.07.17 - Certificate of Conformance	TEVA-MDL2875-00154317
2017.03.15 - Certificate of Conformance	TEVA-MDL2875-00154318
2017.03.15 - Certificate of Conformance	TEVA-MDL2875-00154319
2017.03.09 - Certificate of Conformance	TEVA-MDL2875-00154320
2017.03.20 - Certificate of Conformance	TEVA-MDL2875-00154321
2017.03.15 - Certificate of Conformance	TEVA-MDL2875-00154322
2017.03.20 - Certificate of Conformance	TEVA-MDL2875-00154323
2017.03.21 - Certificate of Conformance	TEVA-MDL2875-00154324
2017.03.15 - Certificate of Conformance	TEVA-MDL2875-00154325
2017.03.15 - Certificate of Conformance	TEVA-MDL2875-00154326
2017.07.17 - Certificate of Conformance	TEVA-MDL2875-00161708
2017.07.31 - Certificate of Conformance	TEVA-MDL2875-00161709
2017.10.05 - Certificate of Conformance	TEVA-MDL2875-00161710
2017.07.17 - Certificate of Conformance	TEVA-MDL2875-00161711
2017.03.15 - Certificate of Conformance	TEVA-MDL2875-00161712
2017.03.15 - Certificate of Conformance	TEVA-MDL2875-00161713
2017.03.09 - Certificate of Conformance	TEVA-MDL2875-00161714
2017.03.20 - Certificate of Conformance	TEVA-MDL2875-00161715
2017.03.15 - Certificate of Conformance	TEVA-MDL2875-00161716
2017.03.24 – certificate of conformance	TEVA-MDL2875-00161717
2017.03.24 – Certificate of conformance	TEVA-MDL2875-00161718
2017.03.24 – Certificate of conformance	TEVA-MDL2875-00161719
2017.03.24 – certificate of conformance	TEVA-MDL2875-00161720
2017.07.21 – certificate of conformance	TEVA-MDL2875-00537628
2017.07.17 – Certificate of conformance	TEVA-MDL2875-00537629
2017.10.25 – Certificate of conformance	TEVA-MDL2875-00537630
2017.07.21 – Certificate of conformance	TEVA-MDL2875-00537631
2017.03.24 – Certificate of conformance	TEVA-MDL2875-00537632

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REVIEW MATERIALS PROVIDED	BATES NOS.
2017.03.15 – Certificate of conformance	TEVA-MDL2875-00537633
2017.03.24 – Certificate of conformance	TEVA-MDL2875-00537634
2017.03.24 – Certificate of conformance	TEVA-MDL2875-00537635
2017.03.24 – Certificate of conformance	TEVA-MDL2875-00537636
2017.03.24 – Certificate of conformance	TEVA-MDL2875-00537637
2017.03.24 – Certificate of conformance	TEVA-MDL2875-00537638
2017.03.24 – Certificate of conformance	TEVA-MDL2875-00537639
2017.03.24 – Certificate of conformance	TEVA-MDL2875-00537640
2017.07.21 – Certificate of conformance	TEVA-MDL2875-00546457
2017.07.25 – Certificate of conformance	TEVA-MDL2875-00546458
2017.10.25 – Certificate of conformance	TEVA-MDL2875-00546459
2017.07.21 – Certificate of conformance	TEVA-MDL2875-00546460
2017.03.24 – Certificate of conformance	TEVA-MDL2875-00546461
2017.03.24 – Certificate of conformance	TEVA-MDL2875-00546462
2017.03.24 – Certificate of conformance	TEVA-MDL2875-00546463
2017.03.24 – Certificate of conformance	TEVA-MDL2875-00546464
2017.03.24 – Certificate of conformance	TEVA-MDL2875-00546465
2017.03.24 – Certificate of conformance	TEVA-MDL2875-00546466
2017.03.24 – Certificate of conformance	TEVA-MDL2875-00546467
2017.03.15 – Certificate of conformance	TEVA-MDL2875-00546468
2017.03.15 – Certificate of conformance	TEVA-MDL2875-00546469
2016.07.25 – Certificate of analysis	TEVA-MDL2875-00676170
2016.07.25 – Certificate of analysis	TEVA-MDL2875-00676174
2016.07.25 – Certificate of analysis	TEVA-MDL2875-00676178
2014.07.17 – Certificate of analysis	TEVA-MDL2875-00676182
2014.07.17 – Certificate of analysis	TEVA-MDL2875-00676186
2014.07.17 – Certificate of analysis	TEVA-MDL2875-00676190
2017.07.13 – Batch manufacturing record	TEVA-MDL2875-00676393
2017.08.08 – Batch record finishing report	TEVA-MDL2875-00676470
2017.08.21 – Bulk finished product specification	TEVA-MDL2875-00676489
2012,11,13 – Batch manufacturing record	TEVA-MDL2875-00676519
Batch manufacturing record audit checklist - production	TEVA-MDL2875-00676617
Bulk finished product specification	TEVA-MDL2875-00676727
2014.09.23 - Test specification and certificate of analysis	TEVA-MDL2875-00676734
2012.09.05 - Test specification and certificate of analysis	TEVA-MDL2875-00676747
2017.07.07 – Test specification and certificate of analysis	TEVA-MDL2875-00676760
OTHER GUIDANCE, STANDARDS AND PUBLICATIONS	
0000 - Unknown - (Huahai Pharma) Evaluation of Products Manufactured in Chuanna Site Regarding NDMA	N/A
0000.00.00 - Low level determination of N-nitrosodimethylamine (NDMA) by chemical lonization GC/MS with large volume injection	N/A
2017.03.31 - Assessment and control of DNA Reactive Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk	TEVA-MDL2875-00118444

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REVIEW MATERIALS PROVIDED	BATES NOS.
2018.09.13 Update on review of valsartan medicines Risk from NDMA remains low, a related substance NDEA also being investigated	TEVA-MDL2875-00423390
MISCELLANEOUS	
All materials cited or referenced in my expert report and curriculum vitae	N/A
All materials cited by Plaintiffs' expert witnesses in their report and exhibits[1]	N/A

[1] This list includes items Plaintiffs' experts relied upon. By so doing, the Teva Defendants and this expert are not waiving any arguments or objections related to admissibility.